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PRINCIPAL INVESTIGATOR: Dr. Christina R. Weltz
Roy Greengrass, M.D.
Stephen Klein, M.D.

CONTRACTING ORGANIZATION: Mount Sinai School of Medicine
New York, New York 10029-6574

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6. AUTHOR(S)
Dr. Christina R. Weltz
Roy Greengrass, M.D.
Stephen Klein, M.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Mount Sinai School of Medicine
New York, New York 10029-6574

E-Mail: Christina.weltz@mountsinai.org

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13. ABSTRACT ***(Maximum 200 Words)***

The goals of the study are to evaluate the role of paravertebral blocks regional anesthesia in patients undergoing operative treatment of breast cancer. Experience to date has shown that this anesthetic modality is safe and effective, and associated with excellent postoperative pain control and minimization of nausea and vomiting associated with general anesthesia. Using a prospective randomized trial carried out at two institutions, we propose to measure quality of life variables including pain, postoperative nausea an vomiting, mood, and functional status in patients undergoing breast surgery with the traditional techniques of general anesthesia versus the region technique of paravertebral block.

The preliminary phase of this trial, which establishes the safety and efficacy of performing the block technique, is complete. We are currently in the study portion of the trial and have consented and randomized a total of 9 patients at one institution thus far. Outcomes and study instruments are detailed in the report. Our collaborating institution, the Mayo Clinic Jacksonville, is awaiting final institutional approval in order to begin recruiting patients.

14. SUBJECT TERMS
Breast Cancer, paravertebral block anesthesia, breast cancer surgery, post operative pain nausea and vomiting, quality of life

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Introduction

General anesthesia is currently the standard anesthetic technique used for modified radical mastectomy, lumpectomy with axillary dissection, and other major operations performed for the treatment of breast cancer. While general anesthesia ensures tolerance of the operative procedure, it is associated with a high incidence of postoperative nausea and vomiting in patients undergoing breast surgery and it is not capable of providing pain relief following emergency. Treatment of pain with parenteral narcotics and supportive care of postoperative nausea prolong hospitalization and diminish quality of life following breast cancer surgery. Paravertebral block is a regional anesthetic technique used historically for the diagnosis and treatment of chronic somatic pain and for operative procedures for the chest and shoulder. The concept of using paravertebral block anesthesia for breast surgery was introduced at Duke University Medical Center in 1994 with the goals of providing safe and effective anesthesia, prolonged postoperative pain relief, reduced nausea and vomiting, and thus improved quality of life following surgical treatment of breast cancer. Retrospective review of a three-year experience with this technique has shown that these goals are being realized (see attached *Annals of Surgery* article). The block provides effective anesthesia in 85% of cases and has a low complication rate of 2.6%. The technique provides sensory block that persists for an average of 23 hours, and therefore the patient experiences minimal surgical pain. Compared to general anesthesia, inpatient narcotic use in those undergoing paravertbral block is reduced from 98% to 25% while anti-emetic use in those undergoing paravertebral block is reduced from 39% to 20%. Patient satisfaction is high, hospital stays are shortened, and we now consider paravertebral block the anesthetic of choice for operative treatment of breast cancer. To test this hypothesis we proposed a prospective randomized clinical trial comparing general anesthesia and paravertebral block. The protocol for this trial was designed such that all aspects perioperative patient care other than the anesthetic used during surgery will be uniform. Narcotic, anti-emetic, and other medication use and responses to questionnaires measure pain, nausea, mood, and other quality of life outcomes during the postoperative interval. Our goal is to definitively evaluate paravertebral block anesthesia in this application and to facilitate widespread use of a new technique that will markedly improve quality of life for most patients with breast cancer.

Body

Statement of work status report:

Task 1. Establish anesthesiologists' proficiency in performing paravertebral block. Months 1-6. Status: Complete

In April of 1999 Dr. Victor Moreno of the Department of Anesthesiology, Mount Sinai Medical Center, traveled to Duke University Medical Center to study the paravertebral block technique. Under the supervision of Dr. Roy Greengrass, Dr. Moreno attained preliminary proficiency sufficient to perform this block independently and train other anesthesiologist. During the subsequent months Dr. Moreno and colleagues performed ten paravertebral blocks on patients undergoing either modified radical mastectomy or lumpectomy with axillary lymph node dissection for the surgical treatment of breast cancer. The efficacy rate of these blocks was 70%; in three cases conversion to general anesthesia was required due to inadequate block at all levels. No complications were encountered while performing these blocks including pneumothorax, infection, intravascular injection of local anesthetic, or epidural spread. Unfortunately in January of 2000 Dr. Moreno left the faculty of Mt. Sinai Medical Center thereby delaying scheduled progress according to the original statement of work. Dr. Janet Pittman from the Department of Anesthesiology at Mt. Sinai Medical Center has taken Dr. Moreno's place in this role. Dr. Pittman was likewise trained in the paravertebral technique under the supervision of Dr. Greengrass at Duke University. She currently employs this technique at Mt. Sinai, has established its safety and efficacy; and has trained one additional colleague, Dr. Barabara Dillos, also of the Mount Sinai Department of Anesthesiology.

Due to the chance in personnel, we anticipated a delay of approximately 10 months in completion of tasks II and III as outlined in the Statement of Work, and so requested (and were granted), a no-cost 18-month extension to the schedule of this trial. The trial's current operational period now extends to October 2002, with an effective study start date of February 2000.

Efforts to introduce the Medical University of South Carolina as a third collaborating site have been postponed due to the unavailability of key personnel. While we are confident current

staffing will prove adequate to complete the study in the allotted time, we are pursuing several other surgeons at Mount Sinai who have expressed interest in contributing their efforts to the study.

Task 2. Preparation of study materials and training of study coordinators. Months 4-6. Status: Complete

The study's existing part-time Clinical Trial Coordinator, Mr. John Arbo, was enlisted full-time in June of 2001. Mr. Arbo has been affiliated with the Department of Surgery at Mount Sinai since January of 2000, when he was brought on part-time to finalize the study's questionnaires, patient consent forms, and study protocol. Mr. Arbo worked closely with Dr. Guy Montgomery of Mount Sinai's Ruttenberg Cancer Center in order to develop an appropriate and comprehensive patient questionnaire. Mr. Arbo also worked closely with Dr. Maryann Pranulis, the U.S. Army's Human Subjects Protection Specialist assigned to this study, in order to finalize the study's protocol and patient consent forms. Protocol amendments received final approval from the U.S. Army Human Subjects Protection Board on June 19, 2001. In preparation for his responsibilities as Trial Coordinator, Mr. Arbo also completed Mount Sinai's certification course in Protection in Human Subjects in Research on June 6, 2001. Mr. Arbo received additional training and authorization to prepare patients for completing study questionnaires and for administering study consent forms. Mr. Arbo holds a Masters degree from Columbia University, has significant health care and database management experience, and is well versed in the intricacies of this particular study. He will remain with the study until its completion, and will contribute to the final analysis and presentation efforts.

Task 3. Subject recruitment and randomization, execution of study protocol, completion of questionnaires. Months 6-20. Status: Ongoing (month 16 – present)

The departure of additional participating personnel within the surgical faculty at Mt. Sinai has reduced the anticipated number of patients that will be recruited into the trial at this center. Similarly delays in patient recruitment are expected on account of Dr. Greengrass's departure from Duke University for his new position with the Department of Anesthesiology at the Mayo Clinic Jacksonville. Dr. Greengrass is currently awaiting final IRB/Army approval for his site-specific protocols and consent form at the Mayo Clinic. We anticipate Mayo will be an active

study site before the new year. Patient recruitment at Mount Sinai began in June of 2001. Initially slow, our recruitment rate has increased, with a total of 9 patients recruited as of November 2001. Study protocol has been successfully executed in all areas, as has completion of study questionnaires and statistical analysis of perioperative data. We anticipate enrollment at Mount Sinai to exceed 20 patients by the end of January 2002. This enrollment rate, together with expected enrollment at the Mayo Clinic, is expected to provide the necessary number of patients to complete the study within the current schedule. To further accelerate recruitment, however, efforts are being made to enlist the support of several additional Mount Sinai attending surgeons. Current results, including negative as well as positive findings are reported below.

Task 4. Data analysis, preparation of reports. Months 20-24. Status: Ongoing (months 19-present)

Preliminary statistical analysis of limited perioperative data has been completed for the study's first 9 patients. Comprehensive analysis of patient questionnaires and perioperative data will be reserved until completion of the trial.

Summary of perioperative data from first 9 patients:

Since June of 2001 a total of nine patients have been consented for participation in the study. Of these nine, 7 were scheduled for lumpectomy with axillary node dissection (LAD), and 2 for modified radical mastectomy (MRM). Of the 7 patients scheduled for LAD, 2 were disqualified from the study: the first patient (randomized to receive the block) was disqualified after being identified as having a schizophrenic disorder that prevented her from completing the questionnaires in an objective manner. The patient's disorder was identified after completion of surgery. The surgery was completed without event, and the patient's questionnaire responses were not entered into the database. The second patient (also randomized to the block) was disqualified on account of an adverse event unrelated to the block. Conversion to Monitored Anesthetic Care was required. The patient's surgery was completed without event, and no post-surgery questionnaires were completed. Details of this adverse event were reported to appropriate personnel at the Mount Sinai IRB and U.S. Army in a timely and comprehensive manner. A copy of the Adverse Event report is attached.

In summary, 6 out of 9 of the patients consented to the study received the block (1/2 for MRM, and 5/7 (3/5 completed questionnaires) for LAD). The block was used successfully in 5 out of 6, or in 83%, of cases.

Data from the 7 patients completing questionnaires can be summarized as follows:

Patients undergoing lumpectomey with axillary node dissection:	
Total number of patients randomized to GA	2
Total number of patients randomized to PVB	3
Patients undergoing modified radical mastectomy:	
Total number of patients randomized to GA	1
Total number of patients randomized to PVB	1
Total number of patients	7

LAD Patients

Average pain score (Memorial Symptom Assessment Scale 1-4) for patients undergoing LAD:

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Paravertebral Block	2.0	1.0	1.3	0.3	0.3	0.3	0.6	0.6
General Anesthesia	2.0	1.5	1.5	1.5	1.0	1.0	0.0	0.0

Average pain score (Visual Analogue Scale 0-10) for patients undergoing LAD:

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Paravertebral Block	4.5	3.0	1.0	0.3	0.3	0.3	0.6	0.3
General Anesthesia	5.0	2.5	3.5	2.5	2.5	0.5	0.0	0.0

Average nausea score (Memorial Symptom Assessment Scale 1-4) for patients undergoing LAD:

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Paravertebral Block	1.0	0.6	0.3	0.0	0.0	0.0	0.0	0.3
General Anesthesia	0.0	2.0	1.0	0.0	0.0	0.0	0.0	0.0

Average nausea score (Visual Analogue Scale 0-10) for patients undergoing LAD:

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Paravertebral Block	3.0	2.3	0.3	0.0	0.0	0.0	0.0	0.3
General Anesthesia	0.0	2.0	1.5	0.0	0.0	0.0	0.0	0.0

All study patients have reported a high level of satisfaction with all aspects of their surgery, study staff, and hospital care. The current low number of patients enrolled allows us to do only limited statistical power analysis. We anticipate that as enrollment increases, pain and nausea scores will approximate previous results from the original Duke University case study with 30 patients (see attached *Annals of Surgery* article)

Key Research Accomplishments

- Employment of full-time Clinical Trial Coordinator for Mount Sinai.
- Poster presentation by Mount Sinai staff of study goals and methods at a Department of Defense funded *Era of Hope* Breast Cancer Conference, Atlanta, June 8-11,2000.
- IRB/Army approval of Mount Sinai revised protocol, patient questionnaires, and consent form.
- Initiation of patient recruitment at Mount Sinai.
- Recruitment at Mount Sinai of nine patients as of November 30, 2001
- Initial statistical analysis of perioperative results from first nine Mount Sinai study patients.
- Mayo Clinic Jacksonville (collaborating research institution) awaiting final IRB/Army approval of site-specific protocol.

Reportable Outcomes

- Poster presentation by Mount Sinai staff of study goals and methods at a Department of Defense funded *Era of Hope* Breast Cancer Conference, Atlanta, June 8-11,2000.

No other reportable outcomes at this time.

Conclusions

Excellent progress has been made in initiating patient recruitment at the Mount Sinai Medical Center. Study protocol, patient questionnaires, and consent forms are being implemented successfully, patient satisfaction is high, and patient enrollment is up. Anticipated obstacles to patient recruitment due to departure of personnel are being dealt with satisfactorily, and will be further assisted by participation of additional surgeons at the Mount Sinai Medical Center, and by introduction of a second recruitment center at the Mayo Clinic Jacksonville in the near future. At this time, given the limited number of patients enrolled in to the study, only limited statistical analysis of perioperative results can be made. The importance and implications of trial results will be determined following additional patient recruitment.

References

1. Weltz CR, Greengrass RA, Lyerly HK. Ambulatory Surgical Management of Breast Carcinoma Using Paravertebral Block. Ann Surg 1995; 222:19026

Appendix

Attachments:

- Copy of revised and IRB/Army approved study protocol
- Copy of revised and IRB/Army approved patient questionnaires
- Copy of revised and IRB/Army approved consent form
- Copy of Adverse Event report
- Copy of 1995 *Annals of Surgery* article on paravertebral block technique

Protocol

A Randomized Prospective Trial Comparing Paravertebral Block and General Anesthesia for Operative Treatment of Breast Cancer

Principal Investigator: Christina R. Weltz, M.D.
Telephone: (212) 241-8026
Fax: (212) 534-2654

Idea Awards Category
Research Period: 2/30/01-6/30/02

Department of Surgery
The Mount Sinai Medical Center
New York, N.Y. 10029

Proposal #BC972205, HSRRB Log. #A-8187, Grant DAMD 17-98-8128.

Co-Investigators: Roy Greengrass, M.D., Mayo Clinic Jacksonville
Guy Montgomery, Ph.D., The Ruttenberg Cancer Center

Trial Coordinator: John E. Arbo, M.A.
Telephone: (917) 334-7094
Fax: (212) 534-2654

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Abstract:

A Randomized Prospective Trial Comparing Paravertebral Block and General Anesthesia for Operative Treatment of Breast Cancer

Principal Investigator: Christina R. Weltz, M.D.

Key Words: Paravertebral block anesthesia, breast cancer surgery, postoperative pain, nausea and vomiting, quality of life

General anesthesia is currently the standard anesthetic technique used for modified radical mastectomy, lumpectomy with axillary dissection, and other major operations performed for the treatment of breast cancer. While general anesthesia ensures tolerance of the operative procedure, it is associated with a high incidence of postoperative nausea and vomiting in patients undergoing breast surgery and it is not capable of providing pain relief following emergence. Treatment of pain with parenteral narcotics and supportive care of postoperative nausea prolong hospitalization and diminish quality of life following breast cancer surgery. Paravertebral block is a regional anesthetic technique used historically for the diagnosis and treatment of chronic somatic pain and for operative procedures of the chest and shoulder. The concept of using paravertebral block anesthesia for breast surgery was introduced at Duke University Medical Center in 1994 with the goals of providing safe and effective anesthesia, prolonged postoperative pain relief, reduced nausea and vomiting, and thus improved quality of life following surgical treatment of breast cancer. Retrospective review of a three year experience with this technique has shown that these goals are being realized. The block provides effective anesthesia in 85% of cases and has a low complication rate of 2.6%. The technique provides sensory block that persists for an average of 23 hours, and therefore the patient experiences minimal surgical pain. Compared to general anesthesia, inpatient narcotic use in those undergoing paravertebral block is reduced from 98% to 25% while anti-emetic medication use is reduced from 39% to 20%. Patient satisfaction is high, hospital stays are shortened, and paravertebral block is now considered by us the anesthetic of choice for operative treatment of breast cancer. To test this hypothesis, we propose a prospective randomized clinical trial comparing general anesthesia and paravertebral block. The protocol for this trial will be designed such that all aspects of perioperative patient care other than the anesthetic used during surgery will be uniform. Narcotic, anti-emetic, and other medication use and responses to questionnaires will measure pain, nausea, mood, and other quality of life outcomes during the postoperative interval. Our goal is to definitively evaluate paravertebral block anesthesia in this application and to facilitate widespread use of a new technique that will markedly improve quality of life for most patients with breast cancer.

Relevance Statement:

During the past five years, more than 180,000 women have been diagnosed with breast cancer anually.[1] Surgery has a role in the treatment of all stages of this disease, and, in 1992, 94% of women diagnosed with breast cancer underwent an operative resection, most commonly modified radical mastectomy followed by lumpectomy with axillary dissection.[2] Quality of life of patients with breast cancer is appropriately receiving increasing attention. Recently, this has focused on surgical treatment, specifically the impact of the operation performed on psychological adjustment, life patterns, fears, and other quality of life outcomes. Studies performed during the 1980's and 90's have focused primarily on mastectomy versus breast-conserving surgery;[3] more recently attention has turned to the impact on quality of life of performing or avoiding axillary lymph node dissection.[4] This research proposal approaches quality of life issues in patients undergoing breast cancer surgery from a different perspective, namely the anesthetic used as opposed to the operation performed.

The standard technique currently used for major breast cancer operations is general anesthesia. General anesthesia, though safe and effective, carries a significant risk of postoperative nausea and vomiting. The incidence in patients undergoing breast cancer surgery is as high as 59%.[5] This prevalence is matched by the clinical significance of postoperative nausea and vomiting, which has been described by patients as more debilitating than the operative procedure itself.[6] Another deficit of general anesthesia is that it provides no mechanism for controlling surgical pain following completion of the operation and emergence from the anesthetic. Pain resulting from a mastectomy or axillary dissection requires narcotic administered intravenously or intramuscularly in virtually all patients. These medications further compound postoperative nausea; they also mandate prolonged hospitalization for patients who, from all other perspectives, are able and desire to return home.

To address these quality of life issues of patients with breast cancer, we have applied a regional anesthetic technique of primarily historical interest, paravertebral block, to an entirely new use, breast cancer surgery. Paravertebral block involves the injection of local anesthetic into the paravertebral space, just lateral to the spinal cord. This space is the anatomic site where the spinal nerve emerges from the intervertebral foramina and divides into dorsal (sensory) and ventral (motor) rami. The paravertebral space is relatively avascular compared to the epidural and intercostal spaces. Therefore, anesthesia injected there diffuses slowly and has the capacity to provide prolonged pain relief. Blocking the lower cervical and upper thoracic spaces effectively anesthetizes the breast, chest wall, and axilla, thus enabling all operative procedures for treatment of breast cancer. Most importantly, by avoiding general anesthesia, nausea, vomiting and other side effects would be markedly reduced. These theoretical considerations prompted our initial investigation of this technique for breast surgery three years ago and they have been realized.[7,8] Paravertebral block has proven safe and effective. Postoperative pain, nausea and vomiting, and length of hospital stay have all been significantly reduced. Paravertebral block has become the anesthetic of choice for breast cancer surgery at our institution. Our hypothesis is that paravertebral block is superior to general anesthesia for operative treatment of breast cancer and is worthy of widespread use. The optimal study design to test this hypothesis is a prospective trial as detailed below, in which patients undergoing surgery for breast cancer are randomized to general anesthesia or paravertebral block, while all other aspects of surgery, recovery, and outpatient care are maintained the same.

The interval surrounding the diagnosis and surgical treatment of breast cancer is characterized by a high incidence of emotional distress, specifically anxiety, depression, and anger.[9] Interventions that improve quality of life during this interval are particularly meaningful, having the potential to raise hope. In studies performed to date, patients undergoing surgery with paravertebral block have enthusiastically reported a high degree of satisfaction with their operative, anesthetic, and recovery experience.[7] We have also observed, though not yet measured, that patients undergoing surgery with paravertebral block have elevated mood, degree of optimism, energy, and activity levels during the postoperative interval compared to patients having general anesthetic. An important goal of this research proposal is to objectively measure functional status, mood, hope, and satisfaction using validated study instruments. Our hypothesis is that paravertebral block anesthesia does positively impact on these, and if widely used in the population undergoing breast cancer surgery, paravertebral block will improve quality of life for the vast majority of patients with breast cancer.

Background:

Significant changes have been made during the past decade in the perioperative care of patients undergoing breast cancer surgery. Prior to the mid-1980's, patients undergoing mastectomy were typically admitted the day prior to surgery and remained hospitalized for between 10 and 14 days, until suction catheters were removed. Clinical studies performed in the mid-1980's showed that same day surgical admission and early discharge with suction catheters in place resulted in significant cost-savings without an increased operative complication rate, and with a high degree of patient satisfaction.[10-13]

Since these findings have been translated into common practice, hospital stays nationwide following major breast surgery have averaged between 2 and 5 days.[10-14] From the perspective of the operative procedure itself, well-informed patients with excellent support at home can undergo breast surgery followed by even shorter hospital stays, including being discharged on the day of surgery or after an overnight hospital stay. This is desirable because it minimizes hospital-based costs for these commonly performed operations, and because early return to familiar surroundings and avoidance of hospitalization speeds operative recovery, increases the patient's sense of control over her disease process, and strengthens emotional ties within the patient's family.[15] Hospitalization following breast surgery, however, is almost always rendered necessary by consequences of general anesthesia, most notably postoperative nausea and vomiting and lack of pain control following emergence from the anesthetic. These features define the recovery interval and render it debilitating. Regional anesthetic alternatives to general anesthesia, specifically intercostal nerve block and high thoracic epidural block, have been described for oncologic and aesthetic breast surgery, with the goals of minimizing postoperative pain and nausea, as well as length of hospital stay. Intercostal block, however, is limited by inadequate anesthesia of the axilla and excessive risk of pneumothorax,[16] while high thoracic epidural is limited by risk of sympathetic blockade, inability to provide prolonged pain control without catheter maintenance, and reports of anesthetic-induced cardiac arrest.[17-18]

Paravertebral block anesthesia is a regional technique in which local anesthesia is injected into the paravertebral space, the area immediately lateral to the spinal cord where spinal nerves emerge from the intervertebral foramina. Attributes of paravertebral block include ease of administration, low morbidity, and potential for prolonged sensory block and hence prolonged pain relief due to the relative avascularity of the paravertebral space. This technique has been described as the gold standard for unilateral operative procedures of the chest or trunk,[19] however it was only first put into practice for breast surgery three years ago, in April 1994, by a group of collaborating anesthesiologists and surgeons at Duke University Medical Center.

To date, we have performed greater than 220 paravertebral blocks for breast cancer surgery, and have twice reviewed our experience with this technique.[7-8] Our experience confirms that the technique is safe and effective. Paravertebral block alone provided effective anesthesia in 85% of 156 reported cases; this efficacy rate increased to 91% when cases requiring supplementation with local anesthetic were included. There have been four anesthetic complications in this series (2.6% incidence): 2 episodes of epidural spread, 1 pneumothorax managed with observation, and 1 episode of epinephrine absorption. Paravertebral block provided sensory block which persisted for an

average of 23 hours, and hence significant pain control. Compared to 100 concurrent patients undergoing breast cancer surgery with general anesthesia, in-hospital narcotic use in patients undergoing paravertebral block was reduced from 98% to 25%. Avoidance of general anesthesia also reduced postoperative nausea and vomiting: anti-emetic medication use was reduced from 39% to 20%. These findings are reflected in duration of hospital stay following surgery. Twenty eight percent of patients undergoing paravertebral block elected to return home on the day of surgery versus 11% of patients in the general anesthesia group; 96% of patients in the paravertebral group returned home within 24 hours of surgery, as opposed to 76% in the general anesthesia group. All of these results were statistically significant. Most importantly, of the 16 patients surveyed in our initial study, all but one rated their operative, anesthetic, and recovery experience with paravertebral block as highly satisfactory. Having documented these attributes of paravertebral block for breast cancer surgery in retrospective review, we now propose a randomized prospective trial comparing this technique with the standard practice of general anesthesia.

Hypothesis/Purpose: The purpose of this study is to measure quality of life variables of pain, nausea and vomiting, mood, and functional status in patients during the interval following breast surgery with the traditional technique of general anesthesia versus the new regional technique paravertebral block. We hypothesize, based on retrospective reviews, that significant differences in postoperative pain, nausea and vomiting, and length of hospital stay will be detected. We also hypothesize that quality of life, as measured by functional status, mood, and return to work and normal activities will be improved in patients undergoing paravertebral block anesthesia.

Specific Objectives:

1) Determine the safety and efficacy of paravertebral block as an anesthetic technique for operative procedures of the breast and axilla. Complete sensory blockade of the breast and axilla are essential for patient comfort, ease of performance, and adequacy of resection for breast surgery, and each of these measures of anesthetic efficacy will be studied. The risks of paravertebral block, which are pneumothorax, epidural spread, intravascular injection of local anesthetic, and infection at the injection site, will be monitored to prospectively determine the safety of this technique.

2) Compare the incidence, severity, and duration of postoperative pain, nausea, and vomiting in patients undergoing breast surgery with paravertebral block versus general anesthesia. Degree, duration, and sensory and affective components of pain and nausea and vomiting will be measured by in- and outpatient medication use, visual analogue scales, and appropriate validated questionnaires. Our hypothesis is that paravertebral block is superior to general anesthesia in minimizing or eliminating pain and nausea and that this will be reflected by the above measures, as well as earlier discharge, quicker return to normal activities, and improved patient satisfaction.

3) Assess the ability to perform breast surgery on an ambulatory or overnight basis. The need for hospitalization following breast surgery reflects primarily the anesthetic, and not the operative experience. By minimizing pain and nausea, paravertebral block has enabled early discharge, provided excellent preoperative teaching and patient acceptance. Patients entered into this study will be eligible for discharge on an ambulatory basis or after overnight stay, and will be offered this option if they fulfill surgical and anesthesia criteria. We hypothesize that paravertebral block will be more conducive to early discharge, resulting in cost savings; that ambulatory discharge will not

result in increased operative morbidity; and that patients will be satisfied with this practice.

4) Compare mood and functional status in patients undergoing breast surgery with paravertebral block versus general anesthesia. We hypothesize that patients undergoing breast surgery using paravertebral block will experience comparable or superior quality of life as measured by mood and functional status during the postoperative interval compared to patients undergoing general anesthesia. These will be measured using appropriate validated questionnaires and a patient satisfaction questionnaire designed for this study.

Methods:

This is a prospective randomized trial comparing paravertebral block and general anesthesia in patients undergoing modified radical mastectomy or lumpectomy with axillary dissection for treatment of breast cancer. The study will be conducted at two medical centers: Mayo Clinic in Jacksonville, FL and the Mount Sinai Medical Center in New York, NY. Beyond the inclusion criteria stated below, this study does not target any specific demographic population.

Inclusion criteria: 1) patients with diagnosis of invasive breast cancer with planned resection using either modified radical mastectomy or lumpectomy with axillary dissection 2) patients willing and able to give informed consent 3) patients willing to be randomized to either general anesthesia or paravertebral block and willing to complete study instruments.

Exclusion criteria: 1) patients with contraindications to placement of paravertebral block: coagulopathy, chronic progressive neuropathy, or infection at proposed injection site 2) patients undergoing bilateral resection or mastectomy followed by immediate reconstructive procedure 3) patients under the age of 18 4) pregnant patients 5) patients without an adequate command of the English language.

Recruitment and Informed Consent Procedures: Patients eligible for the study will be identified by the Principal Investigator during consultation hours at Mt. Sinai's Breast Clinic. The Principal Investigator will have access to all clinical records. Once a patient has been identified as eligible for the study, a member of the research team will explain the study to the patient and give the patient ample opportunity to review the questionnaires they will be asked to complete. If the patient expresses interest in participating in the clinical trial they will be afforded a private room at the Clinic to read, or have read to them, the consent form. This space will be available to the patient for as long as she may require to review the consent form in its entirety. The consent process will be witnessed by a staff member of the clinic who is not associated in any way with the study. Because of the study's inability to ensure the presence of a translator at all stages of the surgery, and during pre- and post-operative questionnaire sessions, patients recruited to this study will be limited to those with an adequate command of the English language. Patients of childbearing years eligible for the study will be asked to take a pregnancy test to confirm that they are not pregnant. Patients will be advised in the consent form to take appropriate precautions to avoid becoming pregnant for the duration of their participation in the study.

Randomization: Randomization to general anesthesia or paravertebral block will be performed by computer program and will be stratified with regard to the operative procedure performed. Hence,

the number of patients in each group undergoing modified radical mastectomy and lumpectomy with axillary dissection will be balanced.

Data collection: At the time of recruitment, the patient will be given a spiral bound questionnaire packet (Packet #1) that will contain the Baseline Questionnaire only. The questionnaire format will be reviewed with the patient by a member of the research staff. The patient will be asked to complete the questionnaire at home within a weeks time, and will be provided a stamped envelope for the purposes of returning the packet. Contact phone numbers for three members of the study's team (including the P.I.) are included in the packet in the event that the patient should have any questions regarding how to complete the questionnaire. Patients may refuse to answer any of the items on the questionnaire. A second packet (Packet #2) containing the remainder of the study's questionnaires will be presented to the patient on the day of surgery. All questionnaires required to be completed immediately pre- or post-operatively are short in length, were designed to require minimum physical effort on behalf of the patient, and will be completed in the presence of and with the assistance of research staff blind to the patient's randomization.

Table 1. Data Collection Schedule

DATA	TIME OF DATA COLLECTION IN RELATION TO SURGERY										
	Baseline	Pre-op	Post-op	PO Day 1	PO Day 2	PO Day 3	PO Day 4	PO Day 5	PO Day 6	PO Day 7	PO 4 weeks
Personal Data	X										
Fam Hx of CA	X										
Med Hx	X										
FACIT-F	X									X	
POMS	X	X								X	
VAS Pain & Nausea Expect.	X										
BPI	X			X	X	X	X	X	X	X	
MSAS			X	X	X	X	X	X	X	X	
VAS Pain & Nausea Actual			X	X	X	X	X	X	X	X	
Medication Record *				X	X	X	X	X	X	X	
Pt Satisfaction Questionnaire										X	
Peri-operative Notes			X								
F/U telephone contact to determine return to work											X

KEY: * = Patient will record medications daily following discharge from hospital; Researchers will record medications administered in the post-anesthesia recovery unit and each day of the hospitalization.

Questionnaire validity and reliability: The Patient Questionnaire was designed to permit complete and accurate data collection while minimizing patient burden. Staff members blind to the type of anesthesia will be available at all times in the hospital to assist the patient with the questionnaires. Contact names and phone numbers for staff members are included in both questionnaire packets so that patients may have questions answered at any time during their participation in the study.

- *Personal Data:* A face-valid questionnaire assessing age, race/ethnicity, education, marital status, employment, height, weight, handedness, and other health and demographic related variables that provide an overview of patient background and may be related to side effect risk. The questionnaire is representative of those commonly used at Mt. Sinai, and takes approximately 3 minutes to complete.

- *Family History of Cancer:* A face-valid questionnaire that assesses a patient's family's history of surgery. Information gained from this questionnaire may relate to side effect risk. The questionnaire is representative of those commonly used at Mt. Sinai and takes approximately 5 to 10 minutes to complete.

- *Medical History:* A face-valid questionnaire that assesses quality of doctor-patient relationship, smoking, drinking, and patients' history of cancer. Information gained from this questionnaire may relate to side effect risk. The questionnaire is representative of those commonly used at Mt. Sinai and takes approximately 5 minutes to complete.

- *FACIT-B (Version 4)*: The validity and reliability of the FACIT-B is well documented. (20) This questionnaire takes approximately 5 minutes to complete.

- *Profile of Mood Survey Short Version (POMS-SV):* A short version (21,22) of the classic mood adjective checklist assesses six affective dimensions (i.e., tension-anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, confusion-bewilderment) and provides a total negative emotions score. The POM-SV has been demonstrated to be a reliable and valid measure with cancer patients (23) and will serve as our primary measure of patients' distress. This questionnaire takes approximately 3 minutes to complete.

- *Visual Analogue Scale (VAS Pain/Nausea Expected):* The VAS (24) will be used to provide a rapid and acute measure of patients' emotional upset and cognitive expectations of post-surgery side effects (e.g., emotional distress, pain, nausea). The format has been found both efficient and valid (e.g. 30, 23, 25, 26) in treatment clinics and in experimental settings. The VAS requires approximately 1-2 minutes to complete.

- *Brief Pain Inventory Short Form (BPI-SF):* The BPI-SF (27) is a short scale designed to assess pain intensity, degree to which prescribed medication provides pain relief, and the extent to which pain interferes with daily activities over the past week. The BPI-SF has been shown to have good psychometric properties (27) and has been recommended for use as a clinical and research tool by the Agency for Health Care Policy and Research (28). The BPI-SF takes approximately 3-5 minutes to complete.

- *Memorial Symptom Assessment Scale (MSAS):* The MSAS is a reliable and well-validated measure designed for use with cancer patients (29). Since the questionnaire is to be administered a short time after surgery, the patient will have the option of completing the questionnaire with the aid of a staff member. Any staff member assisting in such a way will be blind to the type of anesthesia the patient received. The MSAS requires approximately 5-10 minutes to complete.

- *Post Surgery Pain/Nausea VAS Assessment:* The VAS is a widely accepted instrument for measuring pain and nausea. The post surgery VAS uses a "circle the number" method and so is not directly equivalent to the VAS slash mark method used in the pre-operative setting. This was done intentionally to minimize possibly uncomfortable arm movements and to enable staff members to assist patients in completing the questionnaire. Any staff member assisting in such a way will be blind to the type of anesthesia the patient received. The VAS, in either format, is easily understood and takes approximately 1 minute to complete. For these reasons it was selected for use in the post-surgery setting. Since, however, pain and nausea are the two principal variables being considered in this study, it was our opinion that the combined use of the BPI and VAS would provide the most accurate and comprehensive measurement tool. It is also our opinion that once patients have over a full day in the recovery room, that the minor degree of redundancy incurred by completion of both forms will be well tolerated and will not become a burden.

- *Medication Record:* The record is a form that asks the patient to list PO medications taken/24hrs once discharged from the hospital. Form requires 2-3 minutes to complete.

- *Patient Satisfaction Questionnaire (PQS):* The PQS is a face-valid questionnaire adapted from established measures of patient satisfaction used at the Mount Sinai Medical Center. The form requires approximately 5 minutes to complete.

Sequence of events:

1) Diagnosis of breast cancer with plan for surgical treatment via modified radical mastectomy or partial mastectomy with axillary dissection.
2) Determination of eligibility, patient recruitment, and attainment of patient consent to partake in study.
3) Randomize patients to either paravertebral block or general anesthesia; patients will be informed of randomization results within 48 hours of surgery.
4) Preoperative instruction of patient and primary caregiver on home care of wounds and drains.
5) Patient completion of baseline questionnaire. Patients will also be familiarized preoperatively with the questionnaires on pain and nausea that will be used following surgery.
6) Patient admission for surgery; administration of anesthesia and performance of operative procedure.
7) Admission to post-anesthesia care unit (PACU) followed by discharge home or hospital admission.
8) Completion of diaries on medication use during the seven day postoperative interval. Telephone surveys to perform questionnaires on pain, nausea and vomiting, and mood once daily during the 6 day postoperative interval. Completion of satisfaction questionnaire by telephone on day 7 following surgery.
9) Clinic visit 7-10 days postoperatively; assessment of any operative complications will be made.
10) Telephone survey four weeks postoperatively to determine timing of patient return to work.
11) Data analysis using SAS and other appropriate statistical programs.
12) Submission of Volunteer Registry Database (VRDB) sheets annually and at completion of the study

Specific objective #1-Determine safety and efficacy:

Paravertebral block: All patients will be admitted to the hospital on the day of surgery. In the preoperative holding area, patients randomized to paravertebral block anesthesia will be sedated

using intravenous midazolam and fentanyl (both titrated to effect) and undergo block placement by an anesthesiologist certified by the Regional Anesthesia Committee (see below). Blocks will be performed with the patient seated or prone. Sterile skin prep is used. The superior aspect of the spinous process above the nerve to be blocked is located and the overlying skin marked. Approximately 2.5 cm lateral to this, another skin mark is made to localize the transverse process of the immediately caudad vertebra. After skin infiltration with 1% lidocaine, a Tuohy needle is inserted at this level and advanced to identify the transverse process. The needle is then moved caudad off the transverse process and inserted into the paravertebral space. Four milliliters of 0.5% ropivacaine with 1:400,000 epinephrine is injected at each paravertebral space. Spaces Cervical 7-Thoracic 7 will be blocked. Although in no case will the block extend beyond these parameters, experience has shown that that the exact number of spaces to be blocked within this range is a decision best left to the discretion of the anesthesiologist. Patients undergoing paravertebral block will be sedated intraoperatively with diprivan infusion (titrated to effect) and intermittent doses (25 mcg) of fentanyl such that they are arousable. Previously bupivacaine was the anesthetic of choice. We are requesting the change because ropivacaine is equally effective as bupivacaine, but because of its pharmacological makeup it is safer as pertains to the risk of cardiac arythmia

Quality assurance/quality control: Determination of qualification for placing paravertebral block will be made by a Regional Anesthesia Committee, headed by Dr. Roy Greengrass. The committee will be responsible for teaching technique of paravertebral block, certifying anesthesiologists for block placement, and quality control.

Complications of paravertebral block: Patients will be monitored for potential complications of paravertebral block. Suspicion of pneumothorax will be evaluated by chest radiograph and will be noted in the patient data record. Management of pneumothorax (observation or insertion of tube thoracostomy) will also be noted. Episodes and management of intravascular injection of local anesthetic, epidural spread, or bleeding or infection at the injection site as diagnosed by the attending anesthesiologist will be documented. Risks associated with any local anesthesia are central nervous system toxicity, allergic reaction, and cardiac toxicity, primarily arythmia. Serious and unexpected *adverse events* will be immediately reported by telephone to the USAMRMC Deputy Chief of Staff for Regulatory Compliance and Quality (301-619-2165) (non-duty hours call 301-619-2165 and send information by facsimile to 301-619-7803). A written report will follow the initial telephone call within 3 working days. Written report will be sent to the U.S. Army Medical Research and Materiel Command, ATTH: MCMR-RCQ, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

Adequacy of blocks: Anesthesia produced by the block will be evaluated by skin testing in the preoperative holding area. If the block is inadequate, more time will be allowed or supplementation through reinjection will be performed at the discretion of the anesthesia attending. If adequate block cannot be achieved based on skin testing in the preoperative holding area, this will be noted as a failed paravertebral block. Patient will undergo surgery with general anesthesia and the remainder of endpoints will be evaluated.

General Anesthesia: Patients randomized to general anesthesia with endotracheal intubation will undergo induction using diprivan (1.5 -2 mg/kg), and fentanyl (3 μcg/kg). General anesthesia will be

maintained with nitrous oxide/sevoflorane inhalation agents and fentanyl infusion titrated to keep blood pressure no more than 30% above baseline.

Efficacy of paravertebral block: The following intraoperative episodes will be recorded 1) episodes of surgeon's use of local anesthesia - amount used in cc's and number and location of sites injected 2) conversion to general anesthesia 3) need for sedation other than the diprivan and fentanyl.

Risks of conscious sedation and medications associated with trial:

- *Conscious Sedation:* The study's team is aware of the risks associated with conscious sedation. All anesthetic medications will be administered by duly authorized medical staff in a controlled environment with all emergency equipment readily available.

- *Midazolam (Versid):* Risks of central nervous system depression and or anoxia, and serious cardio-respiratory adverse events, will be minimized by continuous cardiorespiratory and peripheral oxygenation monitoring, and the immediate availability of resuscitation equipment and a CPR team. Risks of paradoxical reaction, involuntary tonic and clonic movements, muscle tremor, hyperactivity, and combativeness will be minimized by the immediate availability of specific reversal agents such as Flumanzenil and Narcan. Patients with reduced rate of metabolism in renal disease, hepatic disease, or CHF will receive cautious administration of medication.

- *Fentanyl:* Risk of respiratory depression will be minimized by continuous cardio-respiratory and peripheral oxygenation monitoring, and the immediate availability of resuscitation equipment and a CPR team.

- *Regional anesthesia via cervical-thoracic block:* Risks of inadequate anesthesia (intra-operative pain and distress) will be met by the administration of supplemental anesthesia, and if needed, general anesthesia. Risks of respiratory exertion associated with the cumulative effects on respiratory depression when used in conjunction with conscious sedation will be minimized by continuous cardio-respiratory and peripheral oxygenation monitoring, and the immediate availability of resuscitation equipment and a CPR team. Risks of pneumothorax, intravascular injection, epidural spread, bleeding or infection at the injection site, CNS toxicity, allergic reaction, and cardiac toxicity will be minimized by clinical management by an anesthesiologist certified by the Regional Anesthesia Committee.

- *Ropivacaine:* Risks of CNS toxicity, allergic reaction, and cardiac toxicity will be minimized by continuous cardio-respiratory and peripheral oxygenation monitoring, and the immediate availability of resuscitation equipment and a CPR team.

- *General anesthesia with endotracheal intubation:* Risks of intra-operative cardio-respiratory depression/arrest will be minimized by continuous cardio-respiratory and peripheral oxygenation monitoring by an anesthesiologist certified by the Regional Anesthesia Committee, and the immediate availability of resuscitation equipment and a CPR team. Intra-operative and/or post-operative nausea, vomiting, aspiration will be minimized by use of pain and anti-nausea

medication.

Operative technique: Standard operative techniques will be maintained between general anesthesia and paravertebral block groups. Modified radical mastectomy is performed via an oblique or transverse incision, with creation of skin flaps extending to the clavicle and inframammary fold, and removal of breast tissue to include the pectoralis major fascia. Through the mastectomy incision, at least level 1 and 2 lymph node dissection is performed (level 3 will be included if deemed necessary by surgeon). Closed suction drains will be placed in the axilla and beneath mastectomy flaps. Skin will be closed with staples or subcuticular suture. Axillary dissection as an isolated procedure or in conjunction with local breast excision is performed through curvilinear or transverse incision beneath the axillary hair line. Level 1 and 2 dissections will be performed, with inclusion of level 3 at the surgeon's discretion. A single closed suction axillary drain will be placed. Patients may undergo sentinal-node mapping and biopsy as a component of their axillary surgery at the discretion of the surgeon.

Adequacy of resection: Permanent pathology will be reviewed for all patients. Notation will be made of 1) margins of excised breast tissue - positive or negative for tumor and 2) number of axillary lymph nodes retrieved.

Specific Objective # 2- Assess postoperative pain, nausea and vomiting:

Pain: All patients will be started on a standing order of naprosyn (500 mg orally twice daily for 4 days) with their first postoperative oral intake. All other medications will be prescribed on an as needed basis, but using uniform methodology that enables comparison between groups. While in the recovery room, patients requiring analgesic medication will be given IV boluses of morphine for treatment of pain. Patients admitted to the hospital will be started on a morphine patient controlled analgesia pump. All inpatient pain medication use will be recorded in the data record. At discharge, patients will be prescribed 1) naprosyn as above for completion of 4 days and 2) Tylenol #3 every 3-4 hours, as needed. Patients will be asked to record in their diaries all pain medications taken during the seven days following surgery. Assessment of pain will also be made by daily telephone interviews conducted by the clinical study nurse during the seven postoperative days. Patients will rate both the sensory and affective components of their pain using a visual analogue scale as well as the BPI.

Nausea and vomiting: Patients will be prescribed phenergan IV/PO as needed during the stay in recovery and hospital. They will be prescribed phenergan suppositories on an as needed basis after discharge. Use of these medications will be recorded as for pain medications, described above. Assessment of nausea will also be conducted via the daily telephone interviews. Patients will rate the sensory and affective components of nausea using a visual analogue scale as well as the MSAS.

Specific Objective #3- Compare length of hospital stay following breast surgery:

Preparation for discharge: At the time of entry to the study, patients will be informed that discharge from the recovery room will be a possible outcome. They will be told that the ultimate decision to discharge from recovery or admit to the hospital will be determined in the PACU. In the 1990's, the practice of discharge home with closed-suction drains in place is standard, and excellent

preoperative patient teaching on wound and drain care is requisite. Discharge preparation education for this study will consist of both printed and tape recorded instruction that will be given to patients and their primary planned home caregiver to review during the week before surgery. Individual patient questions regarding wound or drain care will be answered by the clinical study nurse both preoperatively and prior to discharge.

Recovery room and duration of stay: Following completion of surgery, patients will be admitted to the PACU, where they will be assessed every 60 minutes by the clinical study nurse with regard to subsequent disposition. Criteria for discharge home from recovery will be hemodynamic stability, ability to consume oral diet, ability to urinate and ambulate, control of pain with oral agents, lack of nausea and vomiting, and no evidence of excessive drain output as determined by the attending surgeon. Patients considered eligible for discharge home will then be asked to decide if they want to go home or be admitted overnight to the hospital. Patient desire to stay in the hospital will be a criterion for overnight hospitalization. Patients who do not meet discharge criteria on the morning following surgery will remain in the hospital until such criteria are met. Discharge criteria for admitted patients are the same as those described above for use in the PACU. Total length of hospital stay, in hours, will be recorded, and analysis will be made between groups with regard to this variable.

Costs: Costs, broken down into components of professional, operative, anesthetic, and inpatient fees, will be analyzed and recorded at time of hospital discharge and subsequently analyzed between study groups.

Complications: Operative complications will be documented as detailed above in order to determine whether ambulatory discharge or use of the paravertebral block impacts on surgical outcome. Complications following breast procedures are: bleeding (swelling of the wound requiring readmission or reoperation or drain output requiring the same), wound dehiscence (separation of edges of closed wound), wound infection (requires antibiotic treatment), inadvertent drain removal, and seroma (serous fluid collection requiring needle aspiration or drain replacement). Management of wounds and drains will be uniform. All patients will receive one gram of intravenous cefazolin (vancomycin if cephalosporin allergic) at incision; all patients will take cephalexin (500 mg 4 times daily) until drain removal. Drains will be removed when output is less than 30 milliliters per 24 hours. Patients will be seen in clinic 7 -10 days following surgery and subsequently as deemed necessary by the attending surgeon.

Patient satisfaction with timing of discharge: In addition to the quality of life questionnaires described below, patients will complete by telephone interview on postoperative day 7 a satisfaction questionnaire regarding their operative and anesthetic experience, the duration of their stay in the hospital, and the quality of their recovery at home.

Specific Objective #4- Assess mood and functional status:

Evaluation of mood and quality of life: Mood, functional status, and quality of life following breast surgery using paravertebral block versus general anesthesia will be measured using a modified POMS Daily Mood Checklist, the FACIT-B , and the MSAS. These forms are used extensively in cancer clinical trials, with questions related to physical functioning, role functioning,

fatigue, nausea, emotional functioning, social functioning, and global quality of life, all of which are applicable to patients recovering from operative treatment for breast cancer.

Data analysis: Data will be collected in a Microsoft Access database program, and data analysis performed using the SAS statistical package. Univariate and multivariate analysis will be conducted to evaluate the impact of procedure type upon pain, nausea and vomiting, quality of life, patient satisfaction and cost of care. A two sample T-test will be utilized to evaluate the impact of procedure type upon normally distributed continuous variables, and the Kruskal-Wallis test for non-normally distributed continuous variables. Log transformation for cost of care will be performed. Chi-square test will be utilized to evaluate binary variables. Multivariable analysis will be conducted to evaluate the impact of the procedure type upon pain, nausea and vomiting, quality of life, patient satisfaction, and length of stay, controlling for patient characteristics. The results will be presented and published in a surgical peer review forum.

Data security: All data summary and analysis will be done on site at the Mount Sinai Medical Center. During summary and analysis individual participants will be identified by study code number only. No data identifying individual participants will be published or disclosed to any 3rd parties without prior consent of participants. A tracking sheet matching participant names with respective code numbers and the signed consent forms will be kept in a locked drawer. Patient data will be will be kept in a separate locked drawer in individual participant folders baring only corresponding study code numbers. Patient data will be destroyed at completion of the study.

Patient data from remote sites (Mayo Clinic) to be included in this study in the future will be mailed in hard copy via FedEx or another ensured post. Patient data will only contain study code numbers. Hard copies of consent forms and tracking sheets matching names and code number will be mailed separately by FedEx or another ensured post. No data will be transmitted electronically and at no time will participant names and corresponding code number be placed together. Once received by Mt. Sinai tracking sheets and data from remote sites will be filed in the same manner as those from Mt. Sinai.

Data will be entered by study personnel into an onsite computer for summary and analysis. Elements of participant identification including name, social security #, and date of admission, appear only on the tracking sheet and are never entered into the computer. Elements of participant identification included in the computer analysis include only the participant code number and date of birth.

Statistical Power: This study is expected to provide sufficient statistical power to evaluate the impact of procedure type upon the defined outcomes: pain, nausea and vomiting, quality of life, patient satisfaction, and length of hospital stay. Patients will be recruited at the Mayo Clinic in Jacksonville, FL., and the Mount Sinai Medical Center, both of which perform at least 300 modified radical mastectomies or lumpectomy and axillary dissections each year. Assuming an enrollment rate of 35%, 200 patients in total will be enrolled in this study during the interval described in the Statement of Work. Sample size calculations indicate the number of patients required in each arm to demonstrate the noted difference with a power of 80% and a type 1 error of 5%.

VARIABLE	Difference	Std Dev	N(arm)	TOTAL
FACIT-B	10 points	25 points	99	198
BPI	5 points	10 points	63	126
VAS Nausea & Vomiting	0.5 points	1.2 points	92	184
Patient Satisfaction	0.5 points	1.2 points	92	184
Length of Stay	0.5 days	1.0 days	64	128

Procedures for modification of protocol: All modifications to the protocol, consent form and/or questionnaires will be submitted to the HSRRB for review and approval prior to implementation. A list of proposed modifications or amendments to the protocol and an explanation of the need for these modifications will also be submitted. All modifications will also be submitted for approval by the Mount Sinai IRB.

Roles and responsibility of study personnel:

Christina Weltz, M.D., Principal Investigator: Responsible for overall management of trial and all trial related surgery performed at the Mount Sinai Medical Center.

Janet Pittman, M.D., Principal Anesthesiologist: Responsible for placement and management of Paravertebral blocks performed at the Mount Sinai Medical Center.

Guy Montgomery, Ph.D., Behavioral Medicine Specialist: Responsible for development of study questionnaires as well as supervision of data collection and analysis at the Mount Sinai Medical Center.

John Arbo, M.A., Research Coordinator: Responsibilities include recruiting and obtaining consent of patients, collecting of patient data, maintaining of study records, and management and analysis of patient data at the Mount Sinai Medical Center.

Harold Brem, M.D., Medical Monitor: Medical monitor will review all serious and unexpected adverse events associated with the protocol and provide an unbiased written report of the event within 10 calendar days of the initial report. Medical monitor will comment on the outcomes of the adverse event and relationship of the event to the test article. Medical monitor will also indicate whether he concurs with the details of the report provided by the principal investigator.

Volunteer Registry Database:

In compliance with the policy of the U.S. Army Medical Research and Materiel Command data sheets will be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information will be entered into this confidential data base will include the patients name, address, Social Security number, study name and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by USAMRMC; and second, to ensure that the USARMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.

Volunteer Registry Database (VRDB) sheets will be completed accordingly. Once completed, the data sheets will be sent to the following address: Commanding General, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, Maryland 21702-5000

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Breast Surgery Study

Patient Questionnaire
Packet #1

Mount Sinai Medical Center
Christina R. Weltz, M.D.
Department of Surgery

PVB Study
Baseline
Questionnaire Packet

ID # _____

Date ____/____/_____

ID#_____ Date_____

PERSONAL DATA

1. Today's date: ___ ___/ ___ ___/ ___ ___ (m/d/y)

2. Birth date: ___ ___/ ___ ___/ ___ ___ (m/d/y)

3. Height: _____ (ft) _____ (in)

4. Weight: _____ (pounds)

5. Ethnic group (circle one number):

1 White (non-Hispanic)
2 White (Hispanic)
3 Black (non-Hispanic)
4 Black (Hispanic)
5 Asian/Indian
6 Asian or Pacific Islander
7 Native American
8 Other _____
9 Unknown

6. Marital status (circle one number):

1 Never married
2 Currently married
3 Separated
4 Divorced
5 Widowed

7. Who lives with you? (circle all that apply):

1 No one
2 Spouse or partner
3 Roommate(s) (not a partner)
4 Parent(s)
5 Children
6 Other relatives
7 Other _____

8. Level of school completed? (circle one number):

1 Less than 7th grade
2 Junior High school (9th grade)
3 Partial high school (10th or 11th grade)
4 High school graduate
5 Partial college or specialized training
6 Standard college or university graduate
7 Graduate professional training (graduate degree)

ID#_____ Date_____

9. Current employment situation (circle one number):

A. WORKING

1 Full time at job
2 Part time at job

B. ON LEAVE

3 On leave with pay
4 On leave without pay

C. NOT EMPLOYED

5 Seeking work
6 Not seeking work
7 Receiving disability
8 Not self-supporting
9 Homemaker
10 Retired

D. STUDENT

11 Full time
12 Part time

10. Which category best describes your occupation? If you are not currently employed, which best describes your **LAST** job? If you are a homemaker, which best describes your spouse's usual occupation? (circle one number)

1. Professional, Technical, & Related Occupations (as teachers/professors, nurses, lawyers, physicians, & engineers)
2. Manager, Administrator, or Proprietor (as sales managers, real estate agents, or postmasters)
3. Clerical & Related Occupations (as secretaries, clerks or mail carriers)
4. Sales Occupations (as sales persons, demonstrators, agents & brokers)
5. Service Occupations (as police, cooks, or hairdressers)
6. Skilled Crafts, Repairer, & Related Occupations (as carpenters, repairers, or telephone line workers)
7. Equipment or Vehicle Operator & Related Occupations (as drivers, railroad brakemen or sewer workers)
8. Laborer (as helpers, longshoreman, or warehouse workers)
9. Farmer (owners, managers, operators or tenants)
10. Member of the military
11. Other (please describe) _____

12. Approximate annual gross income for your household: (circle one number)

1 Less than $ 10,000
2 $10,000 - $19,999
3 $20,000 - $ 39,999
4 $40,000 - $59,999
5 $60,000 - $100,000
6 Greater than $100,000

13. Which hand do you use to write with? (circle one) LEFT RIGHT

14. Do you consider yourself left or right handed? (circle one) LEFT RIGHT

ID#_____ Date_____

FAMILY HISTORY OF CANCER

We are interested in knowing as much as possible about cancer in your biological relatives. On the following form please indicate your relatives, what type of cancers they had, how old they were at the time of their diagnosis, as we as your age at that time. Please answer to the best of your knowledge. Approximate ages are useful if you cannc be exact, for example, "60's or 70's". Put "?" if you are not sure.

NOTE: Please list separately each cancer for each biological relative. (Please see examples in shaded areas).

	First Cancer			Second Cancer				
Relative Code (see bottom)	Cancer Location Code (see bottom)	Their Age at Diagnosis	Your Age Then	Cancer Location Code (see bottom)	Their Age at Diagnosis	Your Age Then	Outcome: Died from cancer? Yes (Y) No (N)	Were Both Breasts Affected?
1	1	65	26	5	65	36	N	No
6	6	40	18				Y	

Relative Code:

1 = your mother
2 = your sister
3 = your daughter
4 = mother's mother
5 = mother's father
6 = mother's sister
7 = mother's brother
8 = mother's first cousin
9 = other (on mother's side)
10 = your father
11 = your brother
12 = your son
13 = fathers' mother
14 = father's father
15 = father's sister
16 = father's brother
17 = father's first cousin
18 = other (on father's side)
19 = your cousin (mother's sid
20 = your cousin (father's side

Please note that this information is very important and will be kept confidential. Please also take your time completing this form.

☐ CHECK THIS BOX IF NO FAMILY HISTORY OF CANCER

Cancer Code:

1 = Breast
2 = Stomach
3 = Rectal
4 = Other
5 = Ovarian
6 = Colon
7 = Skin
8 = Bladder
9 = Prostrate
10 = Bone
11 = Brain
12 = Lung
13 = Uterine
14 = Pancreatic
15 = Esophagus
16 = Voice Box
17 = Liver
18 = Hodgkin's Disease
19 = Thyroid
20 = Kidney
21 = Non-Hodgkin's Lymphoma
22 = Spine
23 = Leukemia
24 = Parotid gland
25 = Marrow
26 = Lymphoma
27 = Mesothelioma
28 = Lymph Nodes
29 = Cervical
30 = Testicular
31 = Eye
32 = Throat
33 = Bowel
34 = Mouth
35 = Tongue
36 = Renal
37 = Wolf-Parkinson-White Syndrome

ID#_____ Date_____

MEDICAL HISTORY

1. How many times have you been seen by a doctor during the past year for any reason?
   _____ None _____ 1 time _____ 2-5 times _____ 6-12 times _____ over 12 times

2. When was the last time you had a complete physical examination?
   _____ Within the last year(1) _____ 1-2 years ago(2) _____ 2-5 years ago(5) _____ over 5 years ago(6)

3. When was the last time you had a mammogram?
   _____ Within the last year(1) _____ 1-2 years ago(2) _____ 2-5 years ago(5) _____ over 5 years ago(6)
   _____ Never had one(0)

4. During your lifetime, have you smoked at least 100 cigarettes (5 packs)?
   ____ Yes _____ No **(Skip to Question 5)**

   If you answered YES to Question 4,
   a) At what age did you begin smoking regularly? _____ Age in years
   b) How many cigarettes do/did you regularly smoke each day? _____ Cigarettes
   c) Have you smoked in the past month?
      _____ Yes, approximately _____ cigarettes per day.
      _____ No, I quit approximately _____ years ago.

5. Have you consumed any alcoholic beverages in the past month?
   _____ Yes _____ No **(Skip to Question 6)**

   If you answered YES to Question 5,
   a) number of drinks/wk? ____
   (Note: Beer: 1 can = 1 drink; Wine: 1 glass = 1 drink; Hard Liquor: 1 shot = 1 drink)

Circle either "YES" or "NO"

6. Have you ever been disabled for more than 2 months? YES NO

7. Have you had surgery in the last 6 months? YES NO
   If yes, when? Date(s):_____
   For what? _____

8. Have you had a biopsy for any cancer? YES NO
   If yes, when? Date(s):_____
   For what? _____

9. Have you ever had a disease lasting longer than 2 months? YES NO
   If yes, when? Date(s):_____
   What? _____

10. Do you take any medication regularly? Yes No

	Drug	Dose	How Often?
(EXAMPLE)	___Tylenol_____	___2 capsules__	_twice daily__
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

ID#_____ Date_____

11. Are you now having or have you ever had:

Chemotherapy	Yes	No
Radiation therapy	Yes	No
Cortisone	Yes	No

12. Do you consider yourself (circle):

Premenopausal (Continue to get periods)	Postmenopausal (Do not get periods)	Not sure

13. Below are some situations which can cause some people to feel nauseated and/or to vomit. Please indica any of these situations have made <u>you</u> feel nauseated or caused you to vomit by checking one or both columns.

	Nausea has occurred with this item	Vomiting has occurred with this item
Pregnancy	_____	_____
Motion sickness	_____	_____
Drinking alcohol	_____	_____
Anxiety	_____	_____
Odors (perfume, shaving lotion, etc.)	_____	_____
Cigarette smoke	_____	_____
Taking pain medicine	_____	_____
Watching someone else vomit	_____	_____
Sight of blood	_____	_____
Food items (e.g., eggs)	_____	_____
Surgery	_____	_____
Other	_____	_____

ID#_____ Date_____

Facit-F (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	Emotional Well-Being	Not at all	A little bit	Some-what	Quite a bit	Very much
1.	I feel sad	0	1	2	3	4
2.	I am satisfied with how I am coping with my illness	0	1	2	3	4
3.	I am losing hope in the fight against my illness	0	1	2	3	4
4.	I feel nervous	0	1	2	3	4
5.	I worry about dying	0	1	2	3	4
6.	I worry that my condition will get worse	0	1	2	3	4

	Functional Well-Being	Not at all	A little bit	Some-what	Quite a bit	Very much
1.	I am able to work (including at home)	0	1	2	3	4
2.	My work (include work at home) is fulfilling	0	1	2	3	4
3.	I am able to enjoy life	0	1	2	3	4
4.	I have accepted my illness	0	1	2	3	4
5.	I am sleeping well	0	1	2	3	4
6.	I am enjoying the things I usually do for fun	0	1	2	3	4
7.	I am content with the quality of my life right now	0	1	2	3	4

ID#_____ Date_____

Facit-F (Version 4)

Below is a list of statements that other people with your illness have said are important. **By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.**

	Physical Well-Being	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I have a lack of energy	0	1	2	3	4
2.	I have nausea	0	1	2	3	4
3.	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
4.	I have pain	0	1	2	3	4
5.	I am bothered by side effects of treatment	0	1	2	3	4
6.	I feel ill	0	1	2	3	4
7.	I am forced to spend time in bed	0	1	2	3	4

	Social/Family Well-Being	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I feel close to my friends	0	1	2	3	4
2.	I get emotional support from my family	0	1	2	3	4
3.	I get support from my friends	0	1	2	3	4
4.	My family has accepted my illness	0	1	2	3	4
5.	I am satisfied with family communication about my illness	0	1	2	3	4
6.	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box ☐ *and go to the next section*	0	1	2	3	4
7.	I am satisfied with my sex life	0	1	2	3	4

ID#_____ Date_____

Facit-F (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	Additional concerns	Not at all	A little bit	Some-what	Quite a bit	Very much
1.	I have been short of breath	0	1	2	3	4
2.	I am self-conscious about the way I dress.	0	1	2	3	4
3.	One or more of my arms are swollen or tender.	0	1	2	3	4
4.	I feel sexually attractive.	0	1	2	3	4
5.	I am bothered by hair loss.	0	1	2	3	4
6.	I worry that other members of my family might someday get the same illness I have.	0	1	2	3	4
7.	I worry about the effect of stress on my illness.	0	1	2	3	4
8.	I am bothered by a change in weight.	0	1	2	3	4
9.	I am able to feel like a woman.	0	1	2	3	4

ID#_____ Date_____

POMS T/D- Short Version

Below is a list of words that describe feelings people have. Please read each one carefully. Then CIRCLE ONE number which best describes **HOW YOU HAVE BEEN FEELING IN THE PAST WEEK.**

The numbers refer to these phrases:
0 = Not at all
1 = A little
2 = Moderately
3 = Quite a bit
4 = Extremely

1	Tense	0	1	2	3	4	20 Annoyed	0	1	2	3	4
2	Angry	0	1	2	3	4	21 Discouraged	0	1	2	3	4
3	Worn out	0	1	2	3	4	22 Resentful	0	1	2	3	4
4	Unhappy	0	1	2	3	4	23 Nervous	0	1	2	3	4
5	Lively	0	1	2	3	4	24 Miserable	0	1	2	3	4
6	Confused	0	1	2	3	4	25 Cheerful	0	1	2	3	4
7	Peeved	0	1	2	3	4	26 Bitter	0	1	2	3	4
8	Sad	0	1	2	3	4	27 Exhausted	0	1	2	3	4
9	Active	0	1	2	3	4	28 Anxious	0	1	2	3	4
10	On edge	0	1	2	3	4	29 Helpless	0	1	2	3	4
11	Grouchy	0	1	2	3	4	30 Weary	0	1	2	3	4
12	Blue	0	1	2	3	4	31 Bewildered	0	1	2	3	4
13	Energetic	0	1	2	3	4	32 Furious	0	1	2	3	4
14	Hopeless	0	1	2	3	4	33 Full of pep	0	1	2	3	4
15	Uneasy	0	1	2	3	4	34 Worthless	0	1	2	3	4
16	Restless	0	1	2	3	4	35 Forgetful	0	1	2	3	4
17	Unable to concentrate	0	1	2	3	4	36 Vigorous	0	1	2	3	4
18	Fatigued	0	1	2	3	4	37 Uncertain about things	0	1	2	3	4
19	Bushed	0	1	2	3	4						

ID# _____ Date _____

How emotionally upset do you feel right now?

Please put a slash through this line to indicate how upset you feel.

Not at all upset _____ As upset as I could be

ID#_____ Date_____

On your day of surgery, how emotionally upset do you think you will feel?

Please put a slash through this line to indicate how upset you expect to feel.

Not at all upset _____ As upset as I could be

ID#_____ Date_____

After surgery, how emotionally upset do you think you will feel?

Please put a slash through this line to indicate how upset you expect to feel.

Not at all upset

As upset as I could be

ID# _____ Date _____

On your day of surgery, how much pain do you think you will feel?

Please put a slash through this line to indicate how much pain you expect to feel.

No pain at all ——————————————— As much pain as there could be

ID#_____ Date_____

After surgery, how much pain do you think you will feel?

Please put a slash through this line to indicate how much pain you expect to feel.

No pain at all ——————————————— As much pain as there could be

ID#_____ Date_____

On your day of surgery, how nauseated do you think you will feel?

Please put a slash through this line to indicate how nauseated you expect to feel.

Not at all nauseated ——————————— As nauseated as I could be

ID#_____ Date_____

After surgery, how nauseated do you think you will feel?

Please put a slash through this line to indicate how nauseated you expect to feel.

Not at all nauseated ——————————————— As nauseated as I could be

STUDY ID# _____ HOSPITAL # _____

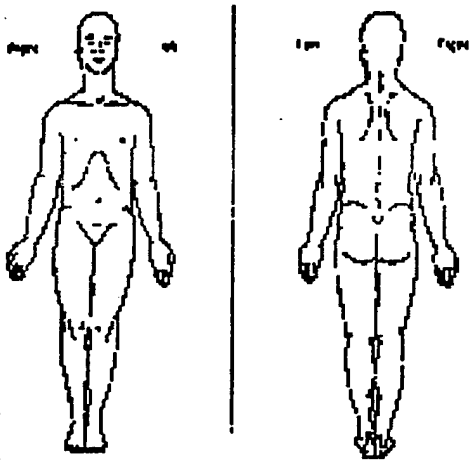
DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

   1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its **worst** in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its **least** in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the **average.**

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have **right now.**

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

_____

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% No Relief 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

C. Walking Ability

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

Breast Surgery Study

Patient Questionnaire
Packet #2

Mount Sinai Medical Center
Christina R. Weltz, M.D.
Department of Surgery

PVB Study
Pre-Surgery
Questionnaire Packet

ID# _____

Date ___/___/___

POMS T/D- Short Version

Below is a list of words that describe feelings people have. Please read each one carefully. Then CIRCLE ONE number which best describes **HOW YOU HAVE BEEN FEELING IN THE PAST WEEK.**

The numbers refer to these phrases:
0 = Not at all
1 = A little
2 = Moderately
3 = Quite a bit
4 = Extremely

1	Tense	0	1	2	3	4	20	Annoyed	0	1	2	3	4
2	Angry	0	1	2	3	4	21	Discouraged	0	1	2	3	4
3	Worn out	0	1	2	3	4	22	Resentful	0	1	2	3	4
4	Unhappy	0	1	2	3	4	23	Nervous	0	1	2	3	4
5	Lively	0	1	2	3	4	24	Miserable	0	1	2	3	4
6	Confused	0	1	2	3	4	25	Cheerful	0	1	2	3	4
7	Peeved	0	1	2	3	4	26	Bitter	0	1	2	3	4
8	Sad	0	1	2	3	4	27	Exhausted	0	1	2	3	4
9	Active	0	1	2	3	4	28	Anxious	0	1	2	3	4
10	On edge	0	1	2	3	4	29	Helpless	0	1	2	3	4
11	Grouchy	0	1	2	3	4	30	Weary	0	1	2	3	4
12	Blue	0	1	2	3	4	31	Bewildered	0	1	2	3	4
13	Energetic	0	1	2	3	4	32	Furious	0	1	2	3	4
14	Hopeless	0	1	2	3	4	33	Full of pep	0	1	2	3	4
15	Uneasy	0	1	2	3	4	34	Worthless	0	1	2	3	4
16	Restless	0	1	2	3	4	35	Forgetful	0	1	2	3	4
17	Unable to concentrate	0	1	2	3	4	36	Vigorous	0	1	2	3	4
18	Fatigued	0	1	2	3	4	37	Uncertain about things	0	1	2	3	4
19	Bushed	0	1	2	3	4							

ID#_____ Date_____

How emotionally upset do you feel right now?

Please put a slash through this line to indicate how upset you feel.

Not at all upset _____ As upset as I could be

ID#_____ Date_____

After surgery, how emotionally upset do you think you will feel?

Please put a slash through this line to indicate how upset you expect to feel.

Not at all upset _____ As upset as I could be

ID#_____ Date_____

After surgery, how much pain do you think you will feel?

Please put a slash through this line to indicate how much pain you expect to feel.

No pain at all _____ As much pain as there could be

ID#_____ Date_____

After surgery, how nauseated do you think you will feel?

Please put a slash through this line to indicate how nauseated you expect to feel.

Not at all nauseated _____ As nauseated as I could be

PVB Study
Post-Surgery Questionnaire

ID# _____

Date ___/___/___

MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

INSTRUCTIONS: We have listed 10 symptoms below. Read each one carefully. If you have had the symptom since surgery, let us know how OFTEN you had it how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

SINCE YOUR SURGERY Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost Always	Slight	Moderate	Severe	Very Severe	Not at all	A little bit	Somewhat	Quite a bit	Very much
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4

POST SURGERY PAIN/NAUSEA VAS ASSESSMENT

1. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

3. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Nausea										Nausea as bad as you can imagine

4. Please rate how unpleasant your nausea is by circling the one number that tells how unpleasant your nausea is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

5. Please rate your emotional upset by circling the one number that tells how emotionally upset you are right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Upset										As Upset as you can imagine

PVB Study
Daily Questionnaire

ID# _____

Date ___/___/___

POST SURGERY PAIN/NAUSEA VAS ASSESSMENT

1. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

3. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Nausea										Nausea as bad as you can imagine

4. Please rate how unpleasant your nausea is by circling the one number that tells how unpleasant your nausea is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

5. Please rate your emotional upset by circling the one number that tells how emotionally upset you are right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Upset										As Upset as you can imagine

Please complete a new sheet each day just before you go to bed.
Medications: Please indicate the name of medication, amount taken, and time you took it

Medication Name	Number or size (mg) of pills taken	Time Taken

MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

INSTRUCTIONS: We have listed 10 symptoms below. Read each one carefully. If you have had the symptom since surgery, let us know how OFTEN you had it how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

SINCE YOUR SURGERY Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost always	Slight	Moderate	Severe	Very Severe	Not al all	A little bit	Somewhat	Quite a bit	Very much
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4

STUDY ID# _____ HOSPITAL # _____

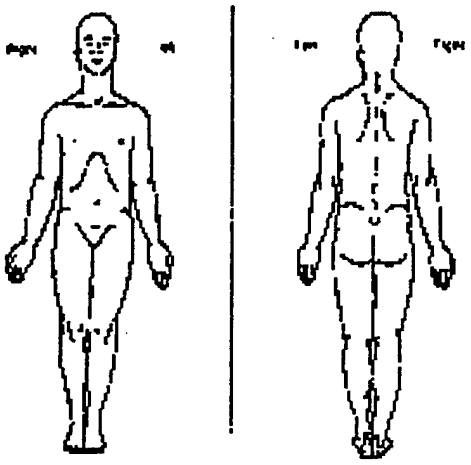
DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

   1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

_____

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% No Relief 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

C. Walking Ability

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

PVB Study
Daily Questionnaire

ID# _____

Date ___/___/___

POST SURGERY PAIN/NAUSEA VAS ASSESSMENT

1. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

3. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Nausea										Nausea as bad as you can imagine

4. Please rate how unpleasant your nausea is by circling the one number that tells how unpleasant your nausea is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

5. Please rate your emotional upset by circling the one number that tells how emotionally upset you are right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Upset										As Upset as you can imagine

Please complete a new sheet each day just before you go to bed.
Medications: Please indicate the name of medication, amount taken, and time you took it

Medication Name	Number or size (mg) of pills taken	Time Taken

MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

INSTRUCTIONS: We have listed 10 symptoms below. Read each one carefully. If you have had the symptom since surgery, let us know how OFTEN you had it how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

SINCE YOUR SURGERY Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost always	Slight	Moderate	Severe	Very Severe	Not al all	A little bit	Somewhat	Quite a bit	Very much
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4

STUDY ID# _____ HOSPITAL # _____

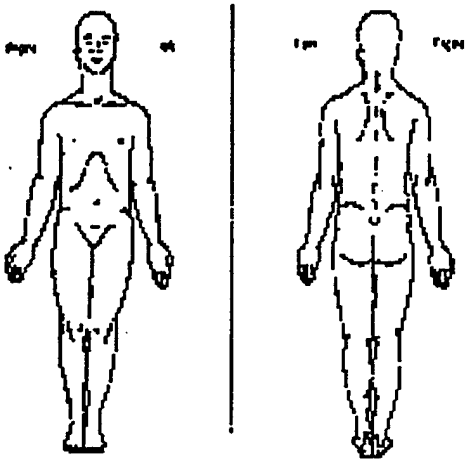
DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

   1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

_____

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% No Relief 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

C. Walking Ability

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

PVB Study
Daily Questionnaire

ID# _____

Date ___/___/___

POST SURGERY PAIN/NAUSEA VAS ASSESSMENT

1. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

3. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Nausea										Nausea as bad as you can imagine

4. Please rate how unpleasant your nausea is by circling the one number that tells how unpleasant your nausea is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

5. Please rate your emotional upset by circling the one number that tells how emotionally upset you are right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Upset										As Upset as you can imagine

Please complete a new sheet each day just before you go to bed.
Medications: Please indicate the name of medication, amount taken, and time you took it

Medication Name	Number or size (mg) of pills taken	Time Taken

MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

INSTRUCTIONS: We have listed 10 symptoms below. Read each one carefully. If you have had the symptom since surgery, let us know how OFTEN you had it how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

SINCE YOUR SURGERY Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost always	Slight	Moderate	Severe	Very Severe	Not al all	A little bit	Somewhat	Quite a bit	Very much
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4

STUDY ID# _____ HOSPITAL # _____

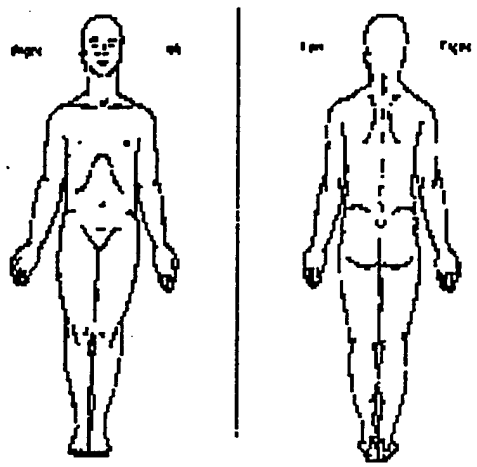
DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

   1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

_____

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No Relief										Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

C. Walking Ability

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not Interfere										Completely Interferes

PVB Study
Daily Questionnaire

ID# _____

Date ___/___/___

POST SURGERY PAIN/NAUSEA VAS ASSESSMENT

1. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

3. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Nausea										Nausea as bad as you can imagine

4. Please rate how unpleasant your nausea is by circling the one number that tells how unpleasant your nausea is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

5. Please rate your emotional upset by circling the one number that tells how emotionally upset you are right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Upset										As Upset as you can imagine

Please complete a new sheet each day just before you go to bed.
Medications: Please indicate the name of medication, amount taken, and time you took it

Medication Name	Number or size (mg) of pills taken	Time Taken

MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

INSTRUCTIONS: We have listed 10 symptoms below. Read each one carefully. If you have had the symptom since surgery, let us know how OFTEN you had it how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

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		Rarely	Occasionally	Frequently	Almost always	Slight	Moderate	Severe	Very Severe	Not at all	A little bit	Somewhat	Quite a bit	Very much
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4

STUDY ID# _____ HOSPITAL # _____

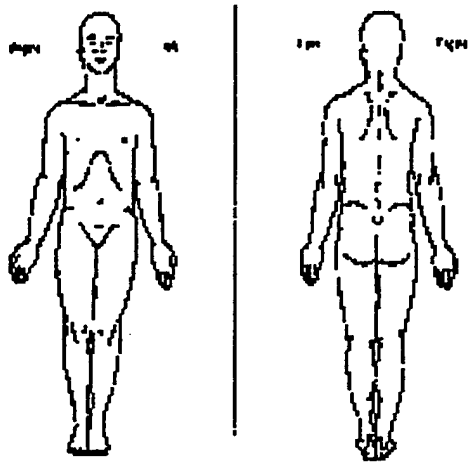
DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

   1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
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0% No Relief 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

C. Walking Ability

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10

Does not Interfere — Completely Interferes

PVB Study
Daily Questionnaire

ID# _____

Date ___/___/___

POST SURGERY PAIN/NAUSEA VAS ASSESSMENT

1. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

3. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Nausea										Nausea as bad as you can imagine

4. Please rate how unpleasant your nausea is by circling the one number that tells how unpleasant your nausea is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

5. Please rate your emotional upset by circling the one number that tells how emotionally upset you are right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Upset										As Upset as you can imagine

Please complete a new sheet each day just before you go to bed.
Medications: Please indicate the name of medication, amount taken, and time you took it

Medication Name	Number or size (mg) of pills taken	Time Taken

MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

INSTRUCTIONS: We have listed 10 symptoms below. Read each one carefully. If you have had the symptom since surgery, let us know how OFTEN you had it how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

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Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
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Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4

STUDY ID# _____ HOSPITAL # _____

DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

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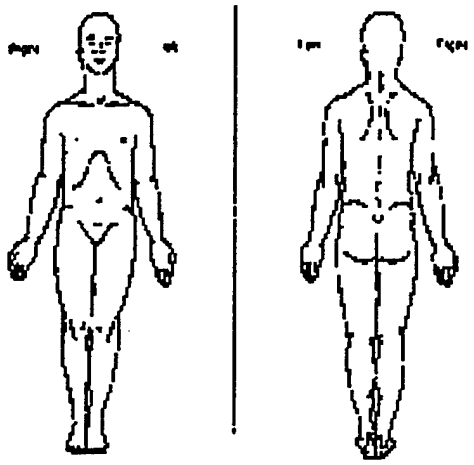
2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

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No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

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Does not Interfere — Completely Interferes

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C. Walking Ability

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F. Sleep

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PVB Study
Daily Questionnaire

ID# _____

Date ___/___/___

POST SURGERY PAIN/NAUSEA VAS ASSESSMENT

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0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

3. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Nausea										Nausea as bad as you can imagine

4. Please rate how unpleasant your nausea is by circling the one number that tells how unpleasant your nausea is right now.

0	1	2	3	4	5	6	7	8	9	10
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5. Please rate your emotional upset by circling the one number that tells how emotionally upset you are right now.

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MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

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SINCE YOUR SURGERY Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost always	Slight	Moderate	Severe	Very Severe	Not al all	A little bit	Somewhat	Quite a bit	Very much
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4

STUDY ID# _____ HOSPITAL # _____

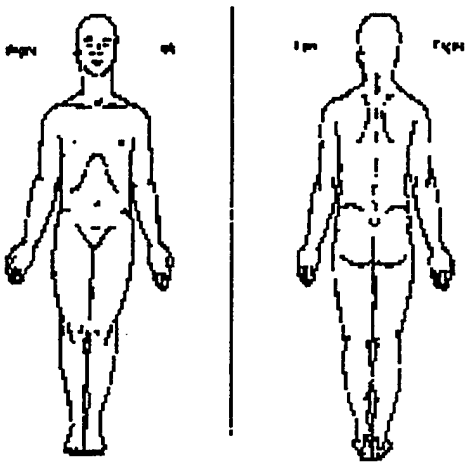
DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

   1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% No Relief 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

C. Walking Ability

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

PVB Study

Day-Seven

Questionnaire

ID# _____

Date ___/___/___

POST SURGERY PAIN/NAUSEA VAS ASSESSMENT

1. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. Please rate how unpleasant your pain is by circling the one number that tells how unpleasant your pain is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

3. Please rate your nausea by circling the one number that tells how much nausea you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Nausea										Nausea as bad as you can imagine

4. Please rate how unpleasant your nausea is by circling the one number that tells how unpleasant your nausea is right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Unpleasant										As Unpleasant as you can imagine

5. Please rate your emotional upset by circling the one number that tells how emotionally upset you are right now.

0	1	2	3	4	5	6	7	8	9	10
Not at all Upset										As Upset as you can imagine

Please complete a new sheet each day just before you go to bed.
Medications: Please indicate the name of medication, amount taken, and time you took it

Medication Name	Number or size (mg) of pills taken	Time Taken

MEMORIAL SYMPTOM ASSESSMENT SCALE - Part 1

ID: DATE:

INSTRUCTIONS: We have listed 10 symptoms below. Read each one carefully. If you have had the symptom since surgery, let us know how OFTEN you had it how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

SINCE YOUR SURGERY Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost always	Slight	Moderate	Severe	Very Severe	Not al all	A little bit	Somewhat	Quite a bit	Very much
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4
Appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhea		1	2	3	4	1	2	3	4	0	1	2	3	4
Sad		1	2	3	4	1	2	3	4	0	1	2	3	4

Facit (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	Emotional Well-Being	Not at all	A little bit	Some-what	Quite a bit	Very much
1.	I feel sad	0	1	2	3	4
2.	I am satisfied with how I am coping with my illness	0	1	2	3	4
3.	**I am losing hope in the fight against my illness**	0	1	2	3	4
4.	I feel nervous	0	1	2	3	4
5.	I worry about dying	0	1	2	3	4
6.	I worry that my condition will get worse	0	1	2	3	4

	Functional Well-Being	Not at all	A little bit	Some-what	Quite a bit	Very much
1.	I am able to work (including at home)	0	1	2	3	4
2.	My work (include work at home) is fulfilling	0	1	2	3	4
3.	I am able to enjoy life	0	1	2	3	4
4.	I have accepted my illness	0	1	2	3	4
5.	I am sleeping well	0	1	2	3	4
6.	I am enjoying the things I usually do for fun	0	1	2	3	4
7.	I am content with the quality of my life right now	0	1	2	3	4

Facit (Version 4)

Below is a list of statements that other people with your illness have said are important. **By circling one (1) number per line, please indicate how true each statement has been for you <u>during the past 7 days</u>.**

	<u>Physical Well-Being</u>	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I have a lack of energy	0	1	2	3	4
2.	I have nausea	0	1	2	3	4
3.	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
4.	I have pain	0	1	2	3	4
5.	I am bothered by side effects of treatment	0	1	2	3	4
6.	I feel ill	0	1	2	3	4
7.	I am forced to spend time in bed	0	1	2	3	4

	<u>Social/Family Well-Being</u>	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I feel close to my friends	0	1	2	3	4
2.	I get emotional support from my family	0	1	2	3	4
3.	I get support from my friends	0	1	2	3	4
4.	My family has accepted my illness	0	1	2	3	4
5.	I am satisfied with family communication about my illness	0	1	2	3	4
6.	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box ☐ *and go to the next section*	0	1	2	3	4
7.	I am satisfied with my sex life	0	1	2	3	4

Facit (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	Additional concerns	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
1.	I have been short of breath	0	1	2	3	4
2.	I am self-conscious about the way I dress.	0	1	2	3	4
3.	One or more of my arms are swollen or tender.	0	1	2	3	4
4.	I feel sexually attractive.	0	1	2	3	4
5.	I am bothered by hair loss.	0	1	2	3	4
6.	I worry that other members of my family might someday get the same illness I have.	0	1	2	3	4
7.	I worry about the effect of stress on my illness.	0	1	2	3	4
8.	I am bothered by a change in weight.	0	1	2	3	4
9.	I am able to feel like a woman.	0	1	2	3	4

POMS T/D- Short Version

Below is a list of words that describe feelings people have. Please read each one carefully. Then CIRCLE ONE number which best describes **HOW YOU HAVE BEEN FEELING IN THE PAST WEEK.**

The numbers refer to these phrases:
0 = Not at all
1 = A little
2 = Moderately
3 = Quite a bit
4 = Extremely

1	Tense	0	1	2	3	4	20	Annoyed	0	1	2	3	4
2	Angry	0	1	2	3	4	21	Discouraged	0	1	2	3	4
3	Worn out	0	1	2	3	4	22	Resentful	0	1	2	3	4
4	Unhappy	0	1	2	3	4	23	Nervous	0	1	2	3	4
5	Lively	0	1	2	3	4	24	Miserable	0	1	2	3	4
6	Confused	0	1	2	3	4	25	Cheerful	0	1	2	3	4
7	Peeved	0	1	2	3	4	26	Bitter	0	1	2	3	4
8	Sad	0	1	2	3	4	27	Exhausted	0	1	2	3	4
9	Active	0	1	2	3	4	28	Anxious	0	1	2	3	4
10	On edge	0	1	2	3	4	29	Helpless	0	1	2	3	4
11	Grouchy	0	1	2	3	4	30	Weary	0	1	2	3	4
12	Blue	0	1	2	3	4	31	Bewildered	0	1	2	3	4
13	Energetic	0	1	2	3	4	32	Furious	0	1	2	3	4
14	Hopeless	0	1	2	3	4	33	Full of pep	0	1	2	3	4
15	Uneasy	0	1	2	3	4	34	Worthless	0	1	2	3	4
16	Restless	0	1	2	3	4	35	Forgetful	0	1	2	3	4
17	Unable to concentrate	0	1	2	3	4	36	Vigorous	0	1	2	3	4
18	Fatigued	0	1	2	3	4	37	Uncertain about things	0	1	2	3	4
19	Bushed	0	1	2	3	4							

Patient Satisfaction Questionnaire

Please indicate your answers by checking the appropriate box.
Overall, how would you rate your satisfaction with:

		Excellent (1)	Very Good (2)	Good (3)	Fair (4)	Poor (5)
1.	The care you received during your hospital stay?					
2.	The anesthesia used for your surgery?					
3.	The care provided by your doctors during your hospital stay?					
4.	The treatment of any pain or discomfort you had during your hospital stay?					
5.	The treatment of any nausea and vomiting you had during your hospital stay?					
6.	The care you received at home since your hospital stay?					
7.	The treatment of any pain or discomfort you've had since you have been home?					
8.	The treatment of any nausea or vomiting you've had since you have been home?					
9.	Discharge instructions: how clearly and completely you were told what to do and what to expect when you left the hospital?					
10.	Coordination of care after discharge: Hospital staff's efforts to prepare you for your recovery at home (i.e., instructions for wound care, emptying of drains, medications, follow-up appointments)?					
11.	Your overall care?					

		A lot shorter than I needed (1)	A little shorter than I needed (2)	About Right (3)	A little longer than I needed (4)	A lot longer than I needed (5)
12.	Do you think the amount of time you spent in the hospital was?					

- Date of return to work/normal activities:_____

STUDY ID# _____ HOSPITAL # _____

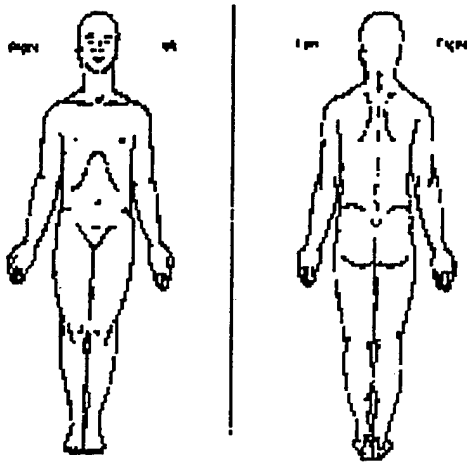
DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these every-day kinds of pain today?

   1. Yes 2. No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its worst in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one nuimber that best describes your pain at its least in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain on the average.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have right now.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

7. What treatments or medications are you receiving for your pain?

_____

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% No Relief 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Complete Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

C. Walking Ability

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

D. Normal Work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not Interfere — Completely Interferes

A randomized prospective trial comparing paravertebral nerve block and general anesthesia for surgical treatment of breast cancer

RESEARCH INFORMATION SHEET:

A. PURPOSE OF THE STUDY

You are being asked to participate in a research study. The purpose of this study is to determine whether the paravertebral nerve block, a form of regional anesthesia is an effective alternative to general anesthesia during surgery for breast cancer. You qualify for participation in this study because you have been scheduled for breast surgery for the treatment of breast cancer.

B. DESCRIPTION OF THE RESEARCH:

General anesthesia (being put to sleep with a breathing tube in place) is currently the standard method of providing anesthesia during mastectomy, lumpectomy and axillary dissection, and other operation performed in the treatment of breast cancer. It is associated with the best chance that the patient feels no pain during surgery and that the patient has no memory of the operation. General anesthesia when used for breast surgery is, however, associated with a 20 to 60% incidence of nausea and vomiting following the completion of the operation. Furthermore, while general anesthesia usually results in no pain during surgery, it cannot control surgical pain following the completion of the surgery. Therefore, following surgery most patients need narcotic pain medication, usually given through an IV or as an injection.

A promising alternative to general anesthesia is the paravertebral nerve block. This is a form of regional anesthesia similar to the anesthesia injected around the spine to ease the pain or labor in childbirth. A paravertebral

nerve block is performed immediately before surgery. An anesthesiologist injects a local anesthetic, or 'numbing medicine,' close to the spine and around the nerves which supply sensation to the area of the breast and axilla (underarm). Usually seven to nine nerves are injected. These blocks are always performed while the patient is sedated or "made sleepy". The surgery is done with the patient awake, but again made sleepy with sedative medicines. The experience with paravertebral block thus far is that pain relief is usually present for 24 hours following the completion of surgery; therefore, need for pain medication after surgery is decreased. Patients having paravertebral block are also less prone to having nausea and vomiting after surgery.

This research is being done here at this institution and will be done at two other medical centers in the near future. The procedures being used in this study were developed at Duke University Medical Center where the procedure has been used extensively in the treatment of patients with breast cancer. Approximately 200 patients will be recruited to join the study

If you volunteer to participate in this research study, all needed tests, surgery and treatments prescribed will occur in the same manner as if you were not participating in the study. The type of surgery you are scheduled to undergo will not change.

The following will occur solely because of your participation in this research project:

1. **You will be assigned by chance to have either general anesthesia or paravertebral block as the type of anesthesia used during your operation. The probability of your having one or the other is 50-50 (like flipping a coin) and will be determined entirely by chance. This process is called randomization.**

2. **If you are assigned to undergo general anesthesia your surgery will proceed as it would if you were not participating in the study.**

3. If you have a paravertebral block, the procedure will be done in the preoperative area before you go into the operating room. After the block is placed, we will check to make sure that you are numb in the areas of the breast and underarm where surgery will be performed and will not feel pain during the procedure. You will then be taken to the operating room where you will be given medication to make you sleepy throughout the operation. The sedation medicine you will be given has a memory loss effect, which means that you may be unable to remember your time in the operating room.

4. Following your surgery, you will be taken to the recovery room. If you are not experiencing significant pain, nausea or vomiting and if you can eat and urinate without difficulty, you will be offered the option to go home that same day. This will be offered to you whether your surgery was done using general anesthesia or paravertebral block. If for any reason you do not desire to go home on the day of surgery, you will be admitted for an overnight stay.

5. When you are discharged you will be prescribed pain medication by your physician which you be able to take as ordered. During the week after your surgery, we will be telephoning you once a day at a time convenient to you, to ask you questions about any pain you are experiencing after surgery, whether you have experienced nausea or vomiting and how you are feeling in general. The questions will require approximately 15-20 minutes to answer. We will also ask you to complete a diary indicating any pain or nausea medications that you are taking at home. This will occur whether your surgery was done using general anesthesia or paravertebral block. Other than the telephone interviews and the diary, your recovery will be entirely like that of someone not participating in this study.

C. COSTS/REIMBURSEMENTS:

You or your insurance company will be responsible for the costs related to the treatment of your breast cancer. You will not receive any payment for participation in this study. There will be no additional charges to you for participating in this study above and beyond those incurred for your routine clinical care.

D. POTENTIAL RISKS AND DISCOMFORTS:

Risks of undergoing a paravertebral block:

The risks of placing a paravertebral block are:

1. **In less than 1% of cases (1 out of 100) placing a paravertebral block can result in a pneumothorax (a puncture of the lung resulting in partial collapse of the lung). If this occurs, it usually requires observation only, and the problem goes away spontaneously. If it does not resolve spontaneously, a plastic tube can be placed to drain the air from the chest cavity. Placing this tube can result in temporary shortness of breath or chest pain, which can be relieved with medication. If a pneumothorax occurs your breast surgery will be delayed until the pneumothorax is resolved. If a pneumothorax occurs, it may also result in prolonged hospitalization.**

2. **Placement of a paravertebral block can result in epidural blockade or a temporary block of the spinal cord which causes temporary difficulty moving and lack of feeling in the legs. This was seen in a 2 of 156 cases in a study conducted at the Duke University Medical Center. If can also lead, temporarily, to low blood pressure or difficulty breathing. Low blood pressure is treated by giving fluids and medication. Difficult breathing may require that a breathing tube (similar to the tube used for general anesthesia) be placed to assist your breathing as well as giving you sedation. In rare situations the breathing tube may be required for up to 24 hours after surgery.**

3. There is a small risk (less than 1 out of 100) of paravetebral block causing infection at the site where the needle is inserted. This would require treatment, usually antibiotics, which may or may not be given while you are in the hospital

4. In approximately 15% (15 of 100 cases), the paravertebral block may not completely numb the area where surgery is performed, in which case you may feel some pain. This will be treated by an injection of local anesthesia by your surgeon. If your surgeon feels it is necessary, or if you request it at this time, you will be put to sleep with general anesthesia and a breathing tube will be placed. An anesthesiologist will be with you during the entire time of your surgery to ensure your comfort.

5. In very rare instances intravascular injection, or injection of an anesthetic into a blood vessel, could cause confusion, tremors or seizures. This has been reported in fewer than 1 out of 500 cases and can be controlled with medications if it occurs.

6. All medications used in this trial are approved by the United States Food and Drug Administration (FDA). Risks associated with medications used in this trial include, but are not limited to, central nervous system depression and cardio-respiratory distress. These risks will be minimized by the continuous monitoring of your status by appropriate medical professionals, and the immediate availability of emergency equipment.

Risks of undergoing general anesthesia:

1. The risks and complications of general anesthesia may include, but are not limited to: temporary sore throat, hoarseness, injury to teeth or airway, pneumonia, lung collapse or other lung problems, injury to arteries or veins, adverse drug reactions, awareness under anesthesia and a very small risk of brain damage or loss of life. These risks will be minimized by the continuous monitoring of your status by appropriate medical professionals, and the immediate availability of emergency equipment.

Risks of loss of privacy and/or personal time:

Once you have agreed to participate in our study, you must be afforded a private room in the clinic to read this consent form, or have it read to you. This space will be made available to you for as long as you require to review this consent form in its entirety. The consent process will be witnessed by a staff member of the clinic who is not associated in any way with the study.

Prior to your surgery you will be asked to complete two questionnaires. The first questionnaire will require about 15-20 minutes of your time, and the second will require about 5 minutes of your time. In the week following your surgery you will contacted once a day at a time convenient to you to answer questions about any pain you are experiencing after surgery. These questions will require about 15-20 minutes of your time to answer. You will also be asked to maintain a daily diary of any pain or nausea medications that you are taking at home. Four weeks after your surgery you will be contacted once and asked if you have returned to work/normal activities. No further demands on your time will be made.

No data identifying you or your participation in this trial will be published or disclosed to any 3rd parties without your prior consent .

Risk of stress associated with participation:

The questionnaires you will be asked to complete were designed to permit accurate data collection while minimizing patient burden. Staff members will be available to you all times to assist with the answering of the questionnaires. Contact names and phone numbers of staff members available to answer any questions you may have are included in both questionnaire packets as well as this consent form. You may withdraw from the study at any time without jeopardizing your treatment. Your doctors may also discontinue your participation as they determine it necessary.

E. POTENTIAL BENEFITS:

There will be no direct benefit to you from participating in this study. However, your participation may help us determine whether general anesthesia or paravertebral block is the preferred type of anesthesia for breast surgery.

F. ALTERNATIVES TO PARTICIPATION (where applicable):

If you decide not to participate in this research study, you will undergo your surgery as scheduled. The type of anesthesia used for your surgery will be based on your choice and advice from your surgeon and anesthesiologist.

G: CONFIDENTIALITY

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. Your medical record in connection with this study will be kept confidential to the extent permitted by law. However, your medical record may be reviewed by government agencies or the agency sponsoring this research, if required by applicable laws or regulations.

H. COMPENSATION/TREATMENT

In the event of injury resulting from your participation in this research study, short term hospitalization and professional attention, if these are required, will be provided at the Mount Sinai Hospital, at no cost to you. Financial compensation from Mount Sinai will not be provided. If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. Weltz at telephone number 212-241-5148.

I. VOLUNTARY PARTICIPATION

Participation in this study is voluntary. If you decide not to participate this will not affect your ability to receive medical care at Mount Sinai or to receive any benefits to which you are otherwise entitled.

A signed copy of this document will be given to you.

J. TERMINATION OF PARTICIPATION (where applicable):

You may withdraw from the study at any time without jeopardizing your treatment. Your doctors may also discontinue your participation as they determine it necessary.

K. CONTACT PERSON

If you have any questions, at any time, about this research, please contact either Dr. Weltz, at telephone number 212-241-5148, or page John Arbo, the Trial Coordinator, at telephone number 917-205-0071. If you still have questions you may discuss them with a member of the Institutional Review Board (the committee which oversees research at Mount Sinai School of Medicine) at telephone number 212-659-8980.

K. PREGNANCY

You should avoid becoming pregnant during of your participation in this study (until 1 week after surgery). To avoid becoming pregnant, you should either abstain from sexual relations or practice a method of birth control.

K. DISCLOSURE OF NEW FINDINGS

Any significant new findings developed during the course of the research which may relate to the your willingness to continue participation will be provided to you.

Representatives from the U.S. Army Medical Research and Materiel Command (and, where applicable, the Food and Drug Administration,) may inspect the records of the research in their duty to protect human subjects.

The Department of Defense is funding this research project. Should you be injured as a direct result of participating in this research of project, you will be provided medical care, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. You should discuss this issue thoroughly with the Principal Investigator before you enroll in this study.

It is the policy of the U.S. Army Medical Research and Materiel Command that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information to be entered into this confidential data base includes your name, address, Social Security number, study name and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by USAMRMC; and second, to ensure that the USARMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.

Authorization to Participate in Research

This form must be signed by the participant/surrogate and the Investigator/delegate

Participant: _____

1. I hereby volunteer to participate in a research program under the supervision of Dr. Weltz and her associates at the Mount Sinai School of Medicine.

2. I acknowledge that I have read, and/or had explained to me in a language I understand, the attached consent document and that Dr. Weltz has explained tome the nature and purpose of these studies. This explanation included a description of the parts of the study that are experimental, the possible discomforts, symptoms, side effects and risk that I might reasonable expect, and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all the questions IU asked were answered to my satisfaction.

3. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies at any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdraw will not affect my ability to receive medical care to which I might otherwise be entitled.

4. I confirm that I have read, or had read tome, this entire authorization and that all blanks or statements that require completion were, in fact, properly completed before I signed this authorization.

For IRB Official Use Only
This Consent Document is approved for use by Mount Sinai's Institutional Review Board (IRB)

From: 3/20/01 To: 1/31/02

Initials of Subject:_____ Initials of Witness:_____ Date:_____

Authorization to Participate in Research (continued)

Research Subject/Surrogate:_____
(signature)

Name:_____
(print)

Relationship:_____
(if signed by a surrogate)

Date:_____

Time:_____

Permanent address of subject:

_____
Number and Street City State Zip Code

Witness:_____
(signature)

Name: _____
(print)

Date:_____

Time:_____

For IRB Official Use Only
This Consent Document is approved for use by Mount Sinai's Institutional Review Board (IRB)

From: 3/20/01 To: 1/31/02

Initials of Subject:_____ Initials of Witness:_____ Date:_____

Authorization to Participate in Research (continued)

For Subjects who are not able to read this consent document themselves, the following must also be completed:

I confirm that I have accurately translated and/or read the information to the subject:

Witness:_____
(signature)

Name: _____
(print)

Address:_____
Number and Street City State Zip Code

ATTESTATION OF PRINCIPAL INVESTIGATOR

I have fully explained to the above volunteer/relative/surrogate the nature and purpose of the above-mentioned research program (including the extent to which the studies are experimental), the possible complications that may arise from both known and unknown causes as a result thereof and the consequences and risks, if any, if the subject decided to discontinue participation. I believe that she/he understands the nature, purpose, and risks of these studies. I have also offered to answer any questions relating to these studies and have fully and completely answered all such questions.

_____
(signature of Principal Investigator/Delegate) (Date)

_____
(print name) (Title)

For IRB Official Use Only
This Consent Document is approved for use by Mount Sinai's Institutional Review Board (IRB)

From: 3/29/01 To: 1/31/02

Initials of Subject:_____ Initials of Witness:_____ Date:_____

Mount Sinai

The Mount Sinai Medical Center

The Mount Sinai Hospital
Mount Sinai School of Medicine

One Gustave L. Levy Place
New York, New York 10029-6574

Harold Brem, M.D.
Divisions of Surgical Oncology
Laproscopic Surgery
Director, Wound Healing

Box 1263
5 East 98th Street
New York, New York 10029-6574

Tel.: (212) 241-3336
Fax: (212) 369-6852

August 29, 2001

RE: GCO #97-368

To Whom It May Concern:

As medical monitor for the above referenced study, I have reviewed the IRB Adverse Event Report for patient Maureen Fox and agreed with its findings.

If you have any questions or concerns regarding this matter, please call me at (212) 241-3336.

Sincerely,

Harold Brem

Harold Brem, MD

IRB stamped cover

Institutional Review Board
Adverse Event Report Form

2001 AUG -2 [illegible]

This form must be attached to all memos/reports describing an adverse event.

GCO	**# 97-368**	**Contact Person**	**John Arbo**
P.I.	**Weltz, Christina**	**Extension**	**-45148**
		Box	**-1263**

The event was related to the subject's participation in the research in the following way: (check one)

Definitely Related:	_____
Probably Related:	_____
Possibly Related:	_____
Definitely Not Related:	__x__

If the adverse event is related to participation in this study, please check or complete one of the following:

The consent form already includes a statement about the possibility of this adverse event and therefore does not need to be modified. __

The consent form has been modified and two copies are enclosed - one with all revisions highlighted and one clean copy to be stamped with IRB approval. ___

Although the event was possibly related to participation in the study, we feel that the consent form does not need to be modified at this time because:

Surgery Date: 7/20/01 Patient: Maureen Fox
Unit # 782968

Mrs. Fox consented on 7/18/01 to partake in Dr. Weltz's clinical trial GCO#97-368. She was scheduled to undergo lumpectomy and axillary lymph node dissection with paravertebral nerve block anesthesia on 7/20/01. Because Mrs. Fox has a history of aplastic anemia, a hematology consult was sought to confirm she had an adequate platelet count to undergo surgery. Hematology consult confirmed no hematologic contraindication to the contemplated surgery. In process of placing the block a subcutaneous hematoma developed at location of PVB attempts. The paravertebral block procedure was aborted to ensure patient safety, and surgery was completed under Monitored Anesthesia Care (MAC). Mrs. Fox was subsequently admitted to hospital, and monitored for any change in neurological condition. Her neurological exam was unremarkable, she presented with no pain or discomfort (hematoma resolved), and she was discharged following day with no complications.

Attachments:

Hematology Report, Kevin Troy, MD	7/18/01
Perioperative Record	7/20/01
Brief Operative Notice	7/20/01

Operative Record, C.Weltz (2 pages)	7/20/01
Anesthesia Report	7/20/01
Post-Anesthesia Care Unit Record	7/20/01
PACU Discharge Assessment Form	7/20/01
Progress Notes (2 pages)	7/20/01-7/21/01
Patient Discharge Plan and Referral Form	7/21/01
Discharge Summary (2 pages)	7/21/01
Discharge Notice	7/21/01
Physicians Attestation Form	7/25/01

If you have any questions please contact:
Shari Melman
IRB Administrator OR
Elan Czeisler
IRB Compliance Officer
Extension 88980 Box 1075

JANET CUTTNER, M.D.
KEVIN M. TROY, M.D. P.C.
HEMATOLOGY
1735 YORK AVENUE NEW YORK, NY 10128
TEL: (212) 860-9055 FAX: (212) 348-0018

July 18, 2001

Christina Weltz, M.D.
Department of Surgery
Mount Sinai Medical Center

Dear Dr. Weltz:

Mrs. Maureen Fox is a patient of mine who will be undergoing lumpectomy and axillary lymph node dissection on July 20, 2001. As you know, she is a 60-year-old woman with a history of aplastic anemia first diagnosed in January 2001. She has been treated with anti-thymocyte globulin, steroids and cyclosporine as well as erythropoietin. Her CBC today shows a hemoglobin of 12.0 gm/dl, a hematocrit of 36%, a white blood cell count of 3,500/ul and a platelet count of 105,000/ul. I have advised Mrs. Fox to take a dose of G-CSF 300 ug tonight and tomorrow night in preparation for surgery. I have also sent a PT and aPTT to Mount Sinai. There is no hematologic contraindication to the contemplated surgery.

Please contact me if you need additional information.

Sincerely,

Kevin M. Troy, M.D.

THE MOUNT SINAI HOSPITAL
New York, New York

PERIOPERATIVE RECORD

FOX, MAUREEN 2GIET
U-0782968 2F06 25 41
S-038582631 0000
A-[illegible]NO 18324 18324 ENI
DR [illegible]

DATE
NAME
UNIT NO. SEX/DOB
SERIAL NO. LOCATION
PHYSICIAN SERVICE

6. DATE (MM, DD, YY)	7. RE NO.	8. CANC.	9. PATIENT CATEGORY	10. CASE TYPE	11. COST CENTER	12. ROOM NO.	13. CASE POSITION	14. O[illegible]ER
07 20 01			0 (Inpatient / Outpatient)	S (Sched., Added, Emergency)	777	A01	04	Y

PLEASE USE 24-HOUR TIME FOR ALL TIME ENTRIES

1720	15. PAT. IN	1340	18. OP. START	2035	21. PAT. DISCH.	3	24. DISCH. TO: 1 = A6RR 2 = A7HA 3 = GPRR 4 = GPHA 5 = P7 6 = ICU 7 = UNIT 8 = MORGUE 9 = ER 10=HOME
1720	16. ANESTH. ST.	2030	19. OP. END		22. RECOVERY IN		25. WOUND CLASSIFICATION 1 = CLEAN 2 = CLEAN/CONTAMINATED 3 = CONTAMINATED 4 = DIRTY OR INFECTED
1835	17. PAT. READY	2035	20. ANESTH. END		23. RECOVERY OUT		

PLEASE LIST NAMES USING LAST NAME, FI, MI

26. ATTENDING SURGEON PROC 1
27. SERVICE 12 — WELTZ C.
28. PROC 1 — Excision Mass of Right Breast. F.S. Sentinal node Biopsy
29. ATT'G SURG. PROC 2 (IF DIFFERENT)
30. SERVICE
31. PROC 2
32. ATT'G SURG. PROC 3 (IF DIFFERENT)
33. SERVICE
34. PROC 3

PROCEDURES

35. SURGICAL RESIDENT/FELLOW
36. SURGICAL RESIDENT — Ehrenberg, D
37. SURGICAL RES./ASST. — J.
38. ATT'G ANESTH. — PITTMAN J.
39. ANESTH. RESIDENT

40. ANESTHESIA TYPE — SO — Mac. See anesthesia Rec
41. PREOPERATIVE DIAGNOSIS — CA Right Breast
42. POSTOPERATIVE DIAGNOSIS — F.S. Mass of Right breast CA Margin grossly free.

SCRUB NURSE(S) — STROMAN M ST. / Manzanales, F 18th St
CIRCUL. NURSE(S) — KENMAI P RN / Nefraadki, K 18th JN

43. CARDIOPULMONARY BYPASS (Y, N) — N SIGN _____, MD
X-RAYS TAKEN — N (Intra-op, Post-op)

PATIENT POSITION — Supine
DRAINS / WOUND SUCTION / PACKING
CATHETERS
MEDICATIONS / IRRIGATIONS — Xylocaine 1% 60 c.c. NaHCO3 60 c.c. and = 60 c.c.

IMPLANT(S), GRAFT(S)	NAME	SERIAL NUMBER	SIZE

SKIN INTACT: PRE-OP ☑ Y ☐ N POST-OP ☐ Y ☐ N — IF NO, EXPLAIN, BELOW

NOTES INCLUDING COMPLICATIONS OF ANESTHESIA, SURGERY

CULTURES? N (Y, N)
SPECIMENS? Y (Y, N)
SENT TO: (PLEASE CIRCLE LABS) EYE PATH, NEURO PATH, FS PATH, SURG. PATH, CYTO, MICRO, CHEMISTRY

INSTRUMENT COUNT CORRECT? (Y,N) — SIGN N/A
SPONGE/NEEDLE COUNT CORRECT? (Y,N) — Y SIGN [illegible] / K. [illegible]

PATIENT'S CHART COPY

NURSE'S SIGNATURE

Mount Sinai

The Mount Sinai Hospital
One Gustave L. Levy Place
New York, New York 10029

FOX, MAUREEN 2105 2GIET 25 41
U-0782968
S-038582631 0001
18324 ENT UNIT NUM
18324
Dr welt

BRIEF OPERATIVE NOTE

Date: 7/20/01 **Time:** 9pm

Preoperative Diagnosis: (RT Breast ca

Postoperative Diagnosis:

Indications:

Procedure: (RT Breast lumpectomy &
(RT axl sentinel node dissection

Classification: ☒ Clean ☐ Clean-Contaminated ☐ Contaminated ☐ Infected

Antibiotic prophylaxis, if indicated: ANCO for MVP prophylaxis.

Surgeons: Welt, Eisenberg

Anesthesia: MAC

Findings: Lumpectomy → gross ⊖ margins
& sentinel ("hot") node removed
No adv. spread.

Specimens sent: (R) lumpectomy ; (R) sentinel node.

Intraoperative Complication, if any:

Close Observations, if Indicated:

Drains, Tubes:

Hardware:

Blood and Fluid losses: Minimal

Volume Replacement: 1.5 c. crystalloid.

Special catheters (venous, arterial, epidural, peritoneal, etc.):

Patient's condition at end of procedure: Pt tolerated procedure well. Transferred to PACU

Print Name: D. EISENBERG M.D. **Signature:** _____ **Code:** 60964

MR1077 (REV10/98)

MOUNT SINAI MEDICAL CENTER
SURGICAL ASSOCIATES

OPERATIVE RECORD

Patient Name:	Unit #:	Date of Operation:
FOX, MAUREEN	0782968	7/20/01

SURGEON: CHRISTINA WELTZ, M.D.

ASSISTANT:

ANESTHETIST:

ANESTHESIA:

SPECIMEN/CULTURE:

PREOPERATIVE DIAGNOSIS:
1. CARCINOMA OF THE RIGHT BREAST

POSTOPERATIVE DIAGNOSIS:
1. CARCINOMA OF THE RIGHT BREAST

NAME OF PROCEDURE:
1. **RIGHT PARTIAL MASTECTOMY WITH LIMITED AXILLARY LYMPH NODE DISSECTION INCLUDING SENTINEL LYMPH NODE MAPPING**

INDICATIONS FOR SURGERY:

The patient has recently been diagnosed with a small carcinoma of the upper outer quadrant of the right breast based on mammographic and sonographic evaluation. A core biopsy has proven the diagnosis. The patient now presents for surgical treatment of this carcinoma in the form of partial mastectomy with axillary lymph node sampling. She has undergone ultrasound-guided wire localization of the tumor, and injection of radioactive nucleide by the nuclear medicine radiologist.

DESCRIPTION OF PROCEDURE:

She presents to the operating room having given informed consent. The patient has a history of aplastic anemia, but her platelet count is within an acceptable range, and her hematologist feels that it would be safe to proceed with the procedure. An attempt is initially made to perform a paravertebral block anesthetic, however this is causing some subcutaneous bleeding, and this is aborted. The patient is administered monitored anesthetic care.

continued

Patient Name:	Unit #:	Date of Operation:
FOX, MAUREEN	0782968	7/20/01

SURGEON:
CHRISTINA WELTZ, M.D.

ASSISTANT:

After infiltration of the skin with lidocaine anesthesia, a horizontal incision is made overlying the site of the tumor. The incision is slightly deepened as the tumor is superficial, and flaps are created in all directions. Using sharp dissection with the cautery to maintain hemostasis due to her coagulopathy, the wire is brought into the operative field. A wide excision of the tissue surrounding the wire is performed. The margins are carefully marked with a silk stitch. The lesion is excised and sent to frozen section pathology. This confirms that it is carcinoma. On gross inspection, the lesion appears to be somewhat close to the deep margin, and hence this margin is re-excised, revealing what appears to be fibrofatty tissue.

The biopsy cavity is thoroughly irrigated and dried after hemostasis is achieved. Using the Neoprobe, radioactivity is detected in the very low axilla near the site of the lumpectomy. Through the same incision, the axillary fascia is opened. Using the Neoprobe, a single radioactive lymph node is identified and excised. No significant background radioactivity is detected. This lymph node is sent to pathology. The biopsy cavity is thoroughly irrigated and dried. A clip is placed at the site of the lumpectomy bed for radiation oncology marking.

The wounds are then closed after the breast tissue is reapproximated with 2-0 Vicryl stitches. The wounds are closed with Vicryl stitches in the dermis and a running subcuticular stitch in the epidermis. The wound is sterilely dressed. The patient tolerated the procedure well, and continued the procedure under monitored anesthetic care. She is brought to the recovery room in stable condition to be monitored.

DD: 07/30/01
DT: 08/01/01
CW:alj/TSPS
#198745

CHRISTINE WELTZ, M.D.

Anesthesia Record

The Mount Sinai Hospital, New York, New York

CompuRecord (R) Anesthesia Information System

PATIENT NAME		
FOX, MAUREEN		
BIRTH DATE	PATIENT AGE	GENDER
06-25-1941	**60 yrs**	**Female**
MEDICAL RECORD #		PATIENT SERIAL #
07829682		
HEIGHT	WEIGHT	BODY SURFACE AREA
164 cm (64.57 in)	**65.7 kg (144.5 lb)**	**1.716 sq meters**
SERVICE DATE	ANESTHETIZING LOCATION	CASE NUMBER
07-20-2001	**OR01 Annen-6**	**2T7KHC0U.106**

Patient Information

Patient Class	**DAS**
NPO Since	**MN 7/19/2001**
ASA Status	**3**
Emergency	**No**

MEDICATIONS	LAST TAKEN	DOSE \ ROUTE \ REASON \ OTC
Cycloserine		**100 mg PO BID**
Prednisone		**5 mg PO QOD**
Zantac		**150 mg PO Daily**
Other (1)		**PROCRIT INJ 2 X WEEK**

DRUG ALLERGIES	TYPE OF REACTION
Morphine	**SEVERE NAUSEA, VOMITING**
Penicillin	

Hematocrit	**36 %**

Practitioners

Attending 1	**PITTMAN,J <esig>**
Primary Surgeon	**Other Surgeon (WELTZ, C)**

Procedure and Diagnosis

Procedure	**RIGHT BREAST LUMPECTOMY, SENTINEL NODE BIOPSY**
PreOp Diagnosis	**RIGHT BREAST CA**
PostOp Diagnosis	**RIGHT BREAST CA**

Other Case Data

Anesthetic Technique	**-FAILED PVB, MAC, GA-**
Position	**Supine**
Arm Positions	**Left Arm Out, Right Arm Out**
Airway Management	**Nasal Cannula [Side-stream capnography]**
Monitors and Equipment	**Standard Monitors (SpO2, EKG, NIBP)** **Blood Pressure Cuff Location [Left arm]** **Blood/Fluid Warmer Info** ◦ **Warmer ID# (HL 90 A 02513)** ◦ **Operating Temperature Range [39-41 deg C.]** ◦ **Audio alarms functional**
IV Site #1	**Position [left wrist]** **Gauge [20 #]**

Fluid Totals

LR	**1500 mL**	**E.B.L**	**75 mL**
Total Fluid Inputs	**1500 mL**	**Total Fluid Outputs**	**75 mL**

Bolus Drug Totals

Midazolam	**6 mg**	**Vancomycin**	**1000 mg**
Fentanyl	**450 µg**	**Diphenhydramine**	**25 mg**
Droperidol	**0.75 mg**	**Ondansetron**	**8 mg**
Propofol	**30 mg**		

Inhalation Drug Totals

O2	**511.5 L**

Anesthesia Times

Start:	**07-20-2001 17:24**	**Finish:**	**07-20-2001 20:45**
		Total:	**03:21**

Surgery Times

Start:	**07-20-2001 18:48**	**Finish:**	**07-20-2001 20:27**
		Total:	**01:39**

Attestation

Attestation Statement	**I was present during the entire procedure**

ATTENDING 1 SIGNATURE	ATTENDING 2 SIGNATURE	RESIDENT 1 SIGNATURE	RESIDENT 2 SIGNATURE
PITTMAN,J <esig>			

Anesthesia Record

The Mount Sinai Hospital, New York, New York

CompuRecord (R) Anesthesia Information System

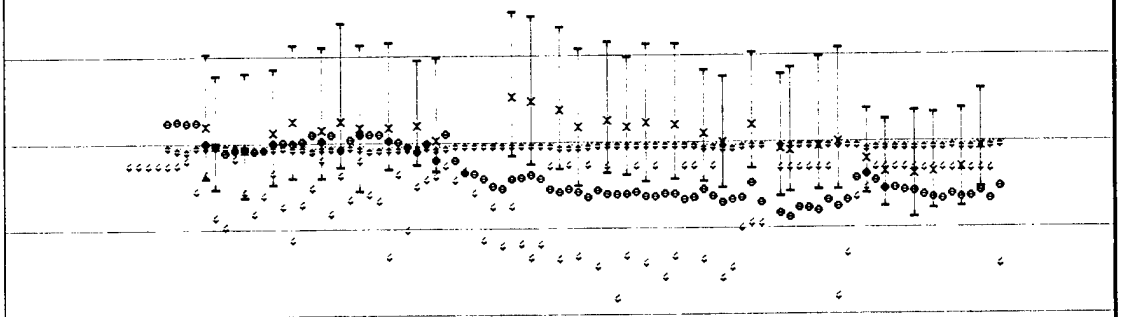
PATIENT NAME **FOX, MAUREEN**		
BIRTH DATE **06-25-1941**	PATIENT AGE **60 yrs**	GENDER **Female**
MEDICAL RECORD # **07829682**		PATIENT SERIAL #
HEIGHT **164 cm (64.57 in)**	WEIGHT **65.7 kg (144.5 lb)**	BODY SURFACE AREA **1.716 sq meters**
SERVICE DATE **07-20-2001**	ANESTHETIZING LOCATION **OR01 Annen-6**	CASE NUMBER **2T7KHC0U.106**

O2	511.5 L	3 L/min
Fentanyl	450 µg	[150] [200] 100
Midazolam	6 mg	2 1 1 2
Propofol	30 mg	30
Vancomycin	1000 mg	1000
Diphenhydramine	25 mg	25
Droperidol	0.75 mg	0.75
Ondansetron	8 mg	8

07-20-2001 17:00 17:30 18:00 18:30 19:00 19:30 20:00 20:30

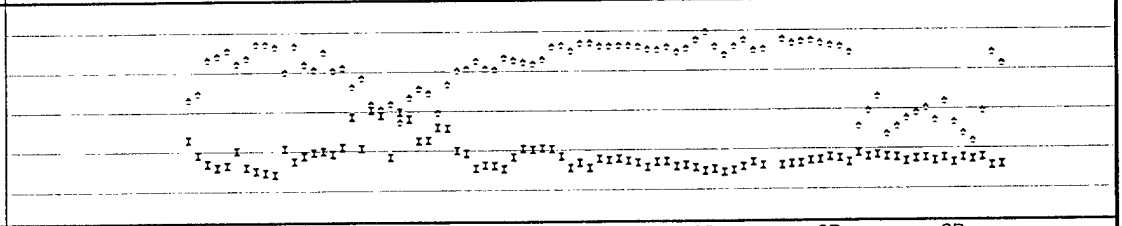
Arterial Pressure
Pulse Rate
SpO2
FiO2

200 190 180 170 160 150 140 130 120 110 100 90 80 70 60 50 40 30 20 10



PIP
Resp Rate
Pulmonary Pressure
CVP
EtCO2

50 45 40 35 30 25 20 15 10 5 0



EKG		SR SR SR SR SR SR SR
Generic Events		<PIR> PST <POR>
ST1	mm	-0.06 0.03 0.06 0.02 0.02 0.07 0.02 0.01 0.04 0.07 0.04 0.03
ST2	mm	-0.25 0.03 -0.11 -0.08 -0.02 0.05 0.01 0.00 -0.00 -0.04 -0.02 -0.02
ST3	mm	0.01 -0.10 -0.03 -0.02 -0.02 -0.06 -0.01 -0.03 -0.03 -0.06 -0.02 -0.04
LR	1500 mL	1000 500
E.B.L	75 mL	75

17:24 Anesthesia Start (AS)
17:24 Patient In OR (PIR)
17:26 Patient ID/Machine Check
17:26 Equipment and machine checklist completed
17:26 Patient identified
17:26 Chart reviewed. No significant interval changes since anesthesia consultation
17:26 Patient prepared to undergo anesthesia
17:30 Sinus Rhythm (SR)
18:00 Sinus Rhythm (SR)
18:30 Sinus Rhythm (SR)
18:34 PT TO RM A1, MONITORS, IV PLACED, TO SITTING POSITION, STERILE PREP, LIDO 1% LOCAL 10 ML INFILT, ATTEMPTED TH PVB SEVERAL LEVELS, T6 LEVEL BLOCKED ONLY, ANATOMY DIFFICULT, PT NOTED TO HAVE HEMATOMA AT LOCATION OF PVB ATTEMPTS. AFTER DISCUSSION WITH PT AND
18:34 DR WELTZ, DECISION MADE TO ABANDON PVB TECHNIQUE AND PROCEED WITH MAC.
18:48 Proc./Surgery Start (PST)
19:00 Sinus Rhythm (SR)
19:24 Sinus Rhythm (SR)
19:50 Sinus Rhythm (SR)
20:15 Sinus Rhythm (SR)
20:27 Proc./Surgery Finish (PF)
20:27 Patient Out Of OR (POR)

Anesthesia Record

The Mount Sinai Hospital, New York, New York

CompuRecord (R) Anesthesia Information System

PATIENT NAME **FOX; MAUREEN**		
BIRTH DATE **06-25-1941**	PATIENT AGE **60 yrs**	GENDER **Female**
MEDICAL RECORD # **07829682**		PATIENT SERIAL #
HEIGHT **164 cm (64.57 in)**	WEIGHT **65.7 kg (144.5 lb)**	BODY SURFACE AREA **1.716 sq meters**
SERVICE DATE **07-20-2001**	ANESTHETIZING LOCATION **OR01 Annen-6**	CASE NUMBER **2T7KHC0U.106**

O2	L/min
Fentanyl	µg
Midazolam	mg
Propofol	mg
Vancomycin	mg
Diphenhydramine	mg
Droperidol	mg
Ondansetron	mg

07-20-2001 to 07-21-2001

20:30 21:00 21:30 22:00 22:30 23:00 23:30 00:00

Arterial Pressure
Pulse Rate
SpO2
FiO2

200 190 180 170 160 150 140 130 120 110 100 90 80 70 60 50 40 30 20 10

PIP
Resp Rate
Pulmonary Pressure
CVP
EtCO2

50 45 40 35 30 25 20 15 10 5 0

EKG

Generic Events — AF

ST1	mm
ST2	mm
ST3	mm
LR	mL
E.B.L	mL

20:45 Anesthesia Finish (AF)

8C7/5A

FOX, MAUREEN
U-0782948 2F06 2NRSU 25 41
S-338582631 0000.
C.WELTZ
23259
23259

Post-Anesthesia Care Unit Record
The Mount Sinai Hospital - New York, NY

Page 1 of 1 Date: 7/20/01

Admission Time: 2040 LOC: (Awake) Arou Uncon

Discharge Time: 2330 LOC: Awake Arou Uncon

Extubation Time: —

Discharged to: (Floor) ICU:___ Home OR

Complications:

Allergies: PCN, Morphine

Stamp Here

Time:	2040	2100	2115	2130	2145	2200	2215	2230	2300	2330
Systolic BP	120	120	120	120	120	120	120	120	120	120
Diastolic BP	70	50	60	60	60	60	50	60	60	60
Heart Rate	80	70	70	75	80	85	88	85	88	90
Neuro checks extremity	✓	✓	✓		✓			✓	✓	
Mean PAP										
CVP										
PCWP										
Cardiac Output										
SpO2	99	100	99	99	99	100	98	94	96	96
FIO2	3L	3L	3L	3L	3L	3L	RA	RA	RA	RA
RR	10	13	11	18	15	16	17	15	16	16
ECG Rhythm	SR			SR				SR		
Temp	36.0							36.2		
pH/PCO2										
PO2/Sat										
HCO3 /BE										
Na+/K+										
Cl-/CO2										
BUN/Cr										
Ca++										
Osm/Gluc										
Hb/Hct										

Symbols
- V Systolic BP
- Λ Diastolic BP
- X Mean BP
- • Heart Rate

Nurse's Notes

2040 Awake & alert. Breathing spontaneously & regularly. O2 sat - 99% c O2 3LPM N.C. Monitored - SR - 76/min. Breast dressing dry & intact. IV site (L) wrist s s/s of infiltration. [illegible]

Voided 100 cc [illegible]

Moving all extremities well.

2055 c/o nausea. Zofran 4mg IV given [illegible]

Ace bandage wrapped around breast to back [illegible]

2330 Report given to 8E RN. Patient stable, still a little bit nauseated. Tolerated crackers & ginger ale in spite of her nausea. No post op bleeding noted. To go to room c NA.
[illegible]

Time	Medication	Dose	Route	Initials	Effect
2055	Zofran	4mg	IV	[illegible]	
2215	Zofran	4mg	IV	[illegible]	fair

Voided 250 cc yellow urine in bedpan.
[illegible]

Anesthesiologist:

Nurse:

D-1-G-1

S-038582631 0000
C.WE.TZ
23259
FOX, MAUREEN
U-07829688 2F06 25 41
S-038582631 0000
C.WE.TZ
23259

THE MOUNT SINAI HOSPITAL
NEW YORK, NEW YORK

PACU DISCHARGE ASSESSMENT FORM

Instructions: **Patients meeting the following PACU discharge criteria may be discharged without additional physician evaluation. For INPATIENTS complete items 1 through 9. For AMBULATORY SURGERY PATIENTS, complete items 1 - 12.**

DISCHARGE CRITERIA	YES	COMMENTS
1. The patient is:		
a. fully awake or easily arousable	✓	
b. able to move all extremities voluntarily or on command, as per baseline	✓	
2. The patient's:		
a. heart rate is within 20% of baseline	✓	
b. blood pressure is within 20% of baseline	✓	
3. The patient's respirations are unlabored.	✓	
4. The patient can breathe deeply and cough freely.	✓	
5. Oxygen saturation (answer a or b):		
a. for inpatients, is > 92% on room air or returns to baseline	✓	
b. for ambulatory surgery patients, is > 95% on room air or returns to baseline		
6. The patient's temperature is ≥ 35.6° and ≤ 38° C.	✓	
7. Bleeding and drainage from surgical sites is/are minimal or acceptable to the primary surgical service.	✓	
8. Postoperative nausea is minimal or adequately treated with medication.	✓	
9. Pain is acceptably controlled with (answer a or b):		
a. for inpatients, intravenous and/or oral medication	✓	
b. for ambulatory surgery patients, oral medication		
CONTINUE FOR AMBULATORY SURGERY PATIENTS		
10. The patient is able to ambulate with a steady gait or has returned to baseline.		
11. Where clinically indicated, the patient is able to void.		
12. The patient will be accompanied home by a responsible escort.		

DISCHARGED FROM (√): ✓ *GP3-PACU* _____ *A6-PACU* _____ *P7*

DISCHARGED TO: 8E *VIA (√):* ✓ *Stretcher* _____ *Wheelchair* _____ *Ambulatory*

DATE: 8/20 *TIME:* 2330 *NURSE:* GDegaetan *RN*
(PRINT NAME)

GDegaetan *RN*
(SIGNATURE)

MR1228(EAPP2/01)

THE MOUNT SINAI MEDICAL CENTER
ONE GUSTAVE L. LEVY PLACE
NEW YORK, NY 10029-6574

PROGRESS NOTES

Enter date, time and title (MD., R.N., L.P.N., S.W., etc) in left hand column.
SIGN each entry with first initial, last name and title.
Doctors please add your dictation code number after signature.

DATE
NAME
FOX, MAUREEN 2CIET
UNIT NO. SEX/DOB
U-0782968 2F06 25 41
SERIAL NO. LOCATION
S-038582631 000?
~~L-RETNO~~
18324 18324 EN1
PHYSICIAN SERVICE
Dr [illegible]

Date Time Title	
	Anesth - Ad [illegible]
7/20/01 1920	pt taken to OR, monitors placed, sterile prep. (R) Th PVB attempted unsuccessfully at several levels (difficult anatomy) able only to block T6. Hematoma noted, regional technique abandoned. Long d/w Dr. [illegible] + patient. Plan is MAC for lumpectomy, then GA for [illegible] dissection. Pt has wire placed by radiology. Message left for pt's hematologist: Dr. Troy (212) 860-9055
	J. [illegible] MD
7/20/01	Surg 4 Post op NOTE
	Pt comfortable in bed, ∅ complaints
	VSS, Afebrile VOIDING - ∅ SOB / [illegible]
	∅N/V
	Lungs - CTA
	Abd - soft NT, ND, + BS
	Incision c̄ dressing - c/d/i
	Ext - 2+ pulses B/L LE
	sensation and motor intact in all four ext.
	A/P 60 y/o ♀ s/p lumpectomy
	Stable
	OOB in AM
	D/C Mon [illegible]
	Neuro Checks
	[signature]

PROGRESS NOTES

D-1-A-2
STD. REG. (10/98)

THE MOUNT SINAI MEDICAL CENTER

ONE GUSTAVE L. LEVY PLACE
NEW YORK, NY 10029-6574

PROGRESS NOTES

Enter date, time and title (MD., R.N., L.P.N., S.W., etc) in left hand column.
SIGN each entry with first initial, last name and title.
Doctors please add your dictation code number after signature.

FOX, MAUREEN 2NRSU
U-0782968 2F06 25 41
S-038582631 0000
C.WELTZ
23259 23259 NBO

DATE
NAME
UNIT NO.
SEX/DOB
SERIAL NO.
LOCATION
PHYSICIAN
SERVICE

Date Time Title	
7/21/00	Focus: New admission
00:00	Data: A+Ox3 s/p Rt Breast Lumpectomy ē axillary node dissection arrived from PACU ē ace bandage wrapped around breast to back dsg dry + intact - IV plasmalyte infusing in (L) arm. Hx of aplastic anemia.
	Action - Pt assisted to bed and made comfortable. Assessed neuro checks of upper and lower extremities + vital signs. Assess level of pain + discomfort - percocet 1 tab po given for c/o pain. IV cont'd ē 0.5% a tromexel [illegible]. Pt took own cyclosporine po on arrival to floor.
	Response - moving all extremities well. vitals. T 37.2 P88. R 20. BP 94/62. Pain reduced adequately ē percocet. Pt voided clear urine. dsg remains dry + intact. no c/o discomfort @ this time. continue to monitor ——— [signature]
7/21/01	Focus: Discharge Teaching
Nsg.	Data: Patient A+Ox3. VSS. ∅ c/o pain.
11:15	S/P (R) Breast Mass Excision + Sentinel Node Biopsy. 7/20/01 (R) Breast, DDI, NVS ⊕ to BUE's. Voiding s̄ difficulty. OOB Ad lib. ∅ N/V.
	Action: Patient Instructed to keep DDI ∅ strenuous Activity to (R) arm. Take prescription as prescribed. Call PMD for F/U visit. Remove Drsg after 3 days. May Shower as per MD. Report any fever, reddness, swelling, drainage or pain.
	Response: Pt verbalized Understanding of all A teaching, Pt accompanied home by Husband. [signature]

THE MOUNT SINAI HOSPITAL, NEW YORK, N.Y.
PATIENT DISCHARGE PLAN AND REFERRAL FORM

The entire sheet must be completed at the time of discharge.
The last copy is to be given to the patient.

FOX, MAUREEN 2NRSU
U-0-82968 2F06 25 41
$-039582631 NOBE
C.WELTZ
23259 23259 10R

Name
Unit #
Sex/DOB
Serial #
Location
Service

DISCHARGE DATE	HOUR	SERVICE / SPECIALTY / PHYSICIAN
7/21/01	11 00	NRSU

DISPOSITION

☒ HOME ☐ OTHER

MODE: ☐ Ambulatory ☒ Wheelchair ☐ Stretcher

PERSON ACCOMPANYING _____

Patient's Telephone (212) 628-2085
Area Code

Relationship Husband

TRANSFER TO: _____ Facility

DIAGNOSES (AS EXPLAINED TO PATIENT/PATIENT SURROGATE)

(R) Breast CA

SURGICAL, OBSTETRICAL AND/OR DIAGNOSTIC PROCEDURES (Include dates):

Excision of (R) Breast Mass F.S.
Sentinel Node Biopsy 7/20/01

DISCHARGE MEDICATIONS/INSTRUCTIONS

① Vicodin ES
1-2 Tablets
Every 4 hours
as needed
for pain

SPECIAL INSTRUCTIONS TO PATIENT e.g. DIET, LIMITATIONS TO PHYSICAL ACTIVITY, WOUND CARE, ETC.

- Keep dressing clean and dry.
- Call PMD for Followup Appt.
- Report any fever, redness, swelling, pain or drainage. any NVS changes
- Take Prescriptions as prescribed.

TO BE FOLLOWED	NAME	PHONE	LOCATION	DATE	TIME
CLINIC/ MSH FACILITY:	Call PMD for Followup Appt.				
PHYSICIAN:	Weltz, C.				
OTHER:					

ALLERGIES/DRUG SENSITIVITIES

PCN

I HAVE RECEIVED THE ABOVE INFORMATION Maureen Fox 7/21/01
PATIENT/DESIGNEE DATE

NURSE'S NOTE (Brief description of patient's status on discharge)

Pt A+OX3. VSS. 0 c/o pain (R) Breast DDI c Tegaderm. NVS (+). Voiding w/o difficulty. Ad lib.

EVALUATION OF PATIENT'S/PATIENT'S SURROGATE UNDERSTANDING OF DISCHARGE INFORMATION:

Patient Verbalized understanding of all DC Teaching.

Primary Nurse/ Designee R.N. Ext. 47939

D-1-A-4D (REV 3/96)
STD. REG. 10/98

Mount Sinai

The Mount Sinai Hospital
One Gustave L. Levy Place
New York, New York 10029

DISCHARGE SUMMARY
PAGE 1 OF 2

FOX, MAUREEN
U-0 [illegible] 2468 2106 2NRSU
S-038582631 NOBE 25 41
C.WELTZ
23259 23259 IOR

DATE
NAME
UNIT NUMBER
SEX/DOB
PHYSICIAN SERVICE

DISCHARGE DATE: 7/21/01

BRIEF HISTORY: (specify chief complaint)
52 yo F c (RT) Breast CA for (PT) breast lumpectomy + axillary sentinel lymph node biopsy

ADMITTING EXAMINATION: (pertinent findings)
Palpable breast mass (RT) UOQ.
Otherwise unremarkable.

HOSPITAL COURSE: (include significant events, treatments, lab, radiology and other diagnostic tests)

7/20/01. OR: Underwent (RT) lumpectomy & (RT) axillary sentinel node dissection. Tolerated procedure well which was performed without complications. Pt observed overnight as she has platelet disorder

7/21/01 Did well overnight. By POD #1, tolerating diet, ambulating, voiding well, minimal pain, no evid of bleeding.

D/c home.
Fu Dr Weltz.

MR1001A (Rev 4/97)
5-0009-14

1. Medical Records 2. Physician

Mount Sinai

The Mount Sinai Hospital
One Gustave L. Levy Place
New York, New York 10029

DISCHARGE SUMMARY
PAGE 2 OF 2

FOX, MAUREEN 2NRSU
U-0782968 2F06 25 41
S-133582631 NOBE
GOLTZ
33259 23259 GF

DATE
NAME
UNIT NUMBER
SEX/DOB
PHYSICIAN SERVICE

PROCEDURES:

7/20/01. RT Breast Lumpectomy with sentinel lymph node biopsy, RT Axilla.

IMMUNIZATIONS GIVEN:

PRINCIPAL DIAGNOSIS: RT Breast Ca.

Comorbidities:

Complications:

DISCHARGE CONDITION: (relative to chief complaint[s])

Stable

DISCHARGE PLAN: (Diet, medication, activity, follow-up)

d/c home
Instruction given.
Vicodin prn pain

Follow-up care with Dr Welk M.D. on: 7/21/01

RESIDENT:

SIGNATURE M.D.

D. Schnabel M.D.
PRINT NAME

DICT # 60864 DATE: 9/11/01

ATTENDING:

SIGNATURE M.D.

PRINT NAME M.D.

DICT # DATE:

MR1001B (Rev 4/97)
5-0009-14

1. Medical Records 2. Physician

THE MOUNT SINAI MEDICAL CENTER
One Gustave L. Levy Place, New York, NY 10029-6574
Mount Sinai School of Medicine • The Mount Sinai Hospital

FOX, MAUREEN 2NRSU
0-0 02968 2F06 25 41
3-038582631 NO8E
C.WELTZ
23259 23259 10R

ADDRESSOGRAPH

The following form shall be used for patients covered under the case payment system:

DATE: 7/21/01

DISCHARGE NOTICE

—READ THIS LETTER CAREFULLY—

IT CONCERNS YOUR PRIVATE INSURANCE BENEFITS OR MEDICAID BENEFITS OR IF YOU ARE UNINSURED.

PRIMARY PAYOR AT DISCHARGE: CIGNA POS

M.R.#: 07829682

ADMISSION DATE: 7/20/01

Dear Patient:

Your doctor and the hospital have determined that you no longer require care in the hospital and will be ready for discharge on:

DISCHARGE DATE ▶ DAY OF WEEK: Saturday DATE: 7/21/01

IF YOU AGREE with this decision, you will be discharged. Be sure you have already received your written discharge plan which describes the arrangements for any future health care you may need.

IF YOU DO NOT AGREE and think you are not medically ready for discharge or feel that your discharge plan will not meet your health care needs, you or your representative may request a review of the discharge decision by contacting the review agent indicated below.

IF YOU WOULD LIKE A REVIEW, you should immediately, but not later than noon of call the telephone number checked off on the IPRA list indicated below.

IF YOU CANNOT REQUEST THE REVIEW YOURSELF, and you do not have a family member or friend to help you, you may ask the hospital representative at extension 48166, who will request the review for you.

IF YOU REQUEST A REVIEW, the following will happen:

1. The review agent will ask you or your representative why you or your representative think you need to stay in the hospital and also will ask your name, admission date and telephone number where you or your representative can be reached.
2. After speaking with you or your representative and your doctor and after reviewing your medical record, the review agent will make a decision which will be given to you in writing.
3. While this review is being conducted, you will not have to pay for any additional hospital days until you have received the review agent's decision.

IF THE REVIEW AGENT AGREES WITH THE DISCHARGE DECISION, you will be financially responsible for your continued stay after noon of the day after you or your representative has been notified of the review agent's decision.

IF THE REVIEW AGENT AGREES THAT YOU STILL NEED TO BE IN THE HOSPITAL:
for Medicaid patients, Medicaid benefits will continue to cover your stay;
for private health insurance patients, coverage for your continued stay is limited to the scope of your private health insurance policy.

NOTE: If you miss the noon deadline mentioned on this notice, you may still request a review. However, if the review agent disagrees with you, you will be financially responsible for the days of care beginning with the proposed discharge date.

If you would like a review of your hospital stay *after* you have been discharged, you may request a review by the review agent within thirty (30) days of the receipt of this notice or seven days after the receipt of a complete bill from the hospital, whichever is later, by writing to the review agent.

I have received this notice on behalf of myself as the patient or as the representative of the patient:

X Maureen Fox (Signature) Self (Relationship) 7/21/01 (Date) 11:00 (Time)

cc: Attending Physician; Hospital Billing Office

IPRA REVIEW AGENTS

FOR ASSISTANCE HELP
The Independent Professional Review Agent (IPRA) for your area and your insurance coverage is

☐ **BLUE CROSS/CIP/SP**
New York County Health Services Review Organization
50 West 23rd Street
New York NY 10010
(212) 897-6000

☐ **Medicaid**-Island Peer Review Org.
1979 Marcus Avenue
Lake Success, NY 11042
(516) 326-6136 (800) 648-4776
Mon.-Fri. 8:30 AM - 4:30 PM

☐ **Medicare**-Island Peer Review
1979 Marcus Avenue
Lake Success, NY 11042
(516) 326-6131
(800) 446-2447

RUN DATE: 07/25/01 16:11

MT. SINAI - *.PRODUCTION *
PHYSICIAN ATTESTATION FORM

MR #: 782968
STAY #: 03

SERIAL #: 38582631
NAME: FOX, MAUREEN

ADMISSION DATE:	07/20/01	TIME: 14:33	PRM F/C:	HEO HMO (NEIC)
DISCHARGE DATE:	07/21/01	TIME: 11:20	SEC F/C:	SLF SELF PAY
BIRTH DATE:	06/25/1941	AGE: 60	SEX:	F
SOCIAL SECURITY #:	148-32-1030		L-O-S:	1
ADMISSION TYPE:	EL	ELECT	ADM SVC:	SUR SURGERY
ADMISSION SOURCE:	1	PHYS REFER	DSC SVC:	SUR SURGERY
DISPOSITION:	HOM	HSC		

DSC/ATT PHYSICIAN: 23259 WELTZ, CHRISTINA

ADMITTING DIAG:	611.72	LUMP OR MASS IN BREAST		
PRINCIPAL DIAG:	174.8	MALIGN NEOPL BREAST NEC		
SECONDARY DIAG: *	284.9	APLASTIC ANEMIA NOS		
SECONDARY DIAG:	424.0	MITRAL VALVE DISORDER		
PRINCIPAL PROC: *	85.21	LOCAL EXCIS BREAST LES	07/20/01	23259
SECONDARY PROC:	40.3	REGIONAL LYMPH NODE EXC	07/20/01	23259

DRG: 259 SUBTOTAL MASTECTOMY FOR MALIGNANCY W CC
MDC: 09 DISEASES & DISORDERS OF THE SKIN, SUBCUTANEOUS TISSUE & BREAST

CODER ID: EMU

DRG RELATIVE WEIGHT: 1.3295
MEAN LENGTH OF STAY: 7.0000
CHART COMPLETION DATE: 07/25/0

ANNALS OF SURGERY
Vol. 222, No. 1, 19–26

Ambulatory Surgical Management of Breast Carcinoma Using Paravertebral Block

Christina R. Weltz, M.D.,* Roy A. Greengrass, M.D.,† and H. Kim Lyerly, M.D.*‡

From the Departments of Surgery, Pathology,‡ and Anesthesiology,† Duke University Medical Center, Durham, North Carolina*

Objective

The authors describe an initial experience using paravertebral block for ambulatory or short-stay operations for breast cancer.

Background

Rising hospital costs have focused attention on limiting the length of stay for patients undergoing surgical treatment of breast cancer. Thus far, ambulatory surgery has been limited by side effects and complications of general anesthesia. Paravertebral block offers the potential benefit of effective analgesia, with limited postoperative nausea and vomiting.

Methods

The medical records of the first 15 patients with breast cancer who underwent 16 major operations for the treatment of breast cancer using paravertebral block were reviewed. Patients were either discharged directly from the recovery room or after overnight hospital admission. The effectiveness of anesthesia, surgical outcome, patient satisfaction, and hospital costs are reviewed.

Results

Paravertebral block achieved effective anesthesia for cancer operations of the breast and axilla; conversion to general anesthesia or supplementation with local anesthesia was not required. There was one postoperative hemorrhage, there were two seromas, and there was one superficial wound infection. Sensory block persisted for an average of 23 hours. Postoperative pain was effectively controlled, in fact, nine patients required no postoperative narcotic for pain control. Nausea and vomiting transiently afflicted three patients and prompted overnight observation in one patient originally scheduled for immediate discharge. Fourteen patients (93%) rated their experience as "very satisfactory."

Conclusion

Breast operations for the surgical management of breast cancer using paravertebral block can be performed safely, with great patient satisfaction, and with potential for significant cost savings.

Breast cancer will affect more than 182,000 patients in the United States in 1995. Effective management of breast cancer usually involves surgical intervention in the form of wide local excision and axillary lymph node dissection, mastectomy, or modified radical mastectomy. Hospital costs are a significant component of the overall costs for the management of breast cancer and comprised 38.4% of total health-care expenditures in 1991.[1] This, coupled with fixed payments imposed by diagnostic-related groups and third-party payers, has prompted strategies to reduce the duration of hospital admissions. The large number of patients hospitalized annually for surgical treatment of breast cancer has focused efforts at containing hospital costs and reducing length of stay in this population.[2]

Studies performed during the 1980s established same-day admission and early discharge with suction catheters in place, thereby achieving significant cost savings nationwide.[3–6] Furthering cost reductions by performing breast surgery on an ambulatory status, however, has been limited by postoperative nausea, vomiting, and pain. General anesthesia can be implicated primarily in these effects. It has emetic properties, with the highest incidence among women and breast surgery patients.[7] Furthermore, neither general anesthesia nor high thoracic epidural can achieve postoperative pain control.

Regional anesthesia in the form of thoracic paravertebral block provides extensive anesthesia for operative breast procedures, with reduced nausea and vomiting and prolonged pain relief. This technique involves injection of local anesthetic at the anatomic site where the spinal nerve emerges from the intervertebral foramina and divides into dorsal and ventral rami. This space also contains the sympathetic trunk and rami communicantes (Fig. 1); hence, infiltration with local anesthetic achieves unilateral sensory, motor, and sympathetic blockade. Paravertebral block has been used as a somatic nerve block in surgery of the chest and shoulder and as a sympathetic blockade for diagnosing and controlling chronic pain.[8–11] During the early 20th century, paravertebral block was used to treat postmastectomy breast cancer patients with chest wall pain caused by regional recurrence.[8]

Paravertebral block has been employed in the setting of ambulatory surgery or planned overnight admission for observation of patients undergoing simple mastectomy, modified radical mastectomy, and wide local excision with axillary dissection. This review focuses on the effectiveness of anesthetic technique, surgical outcome, patient satisfaction, and hospital costs of this practice.

Address reprint requests to H. Kim Lyerly, M.D., Box 2606, Duke University Medical Center, Durham, NC 27710.
Accepted for publication January 23, 1995.

METHODS

The hospital records of all patients undergoing major breast surgical procedures under paravertebral block in the practice of an individual surgeon (HKL) were reviewed. Between April and August 1994, this technique was employed in 16 procedures performed on 15 patients (Table 1). Operative procedures were wide excision and axillary lymph node dissection (seven patients), modified radical mastectomy (five patients), and simple mastectomy (four patients). All patients were women. The average age was 57 years and ranged from 39 to 77 years. Preoperative diagnoses were extensive ductal carcinoma *in situ* (one patient), stage I breast cancer (eight patients), and stage II breast cancer (six patients). Thirteen patients had undergone prior ipsilateral breast biopsy, and one had undergone prior biopsy followed by re-excision and axillary dissection. In 11 cases, the patients were scheduled to undergo surgery on an ambulatory basis. Five patients were scheduled to be admitted overnight to a postoperative observation room. This decision was based on patient preference. Observation rooms are designed for postoperative hospitalizations of less than 24 hours, and a daily room rate of $490.00 is charged on a prorated hourly basis.

All patients presented on the day of surgery. Paravertebral block was performed in the preoperative holding area with hemodynamic and pulse oximetry monitoring. The patients were either seated or prone for placement of the block and were sedated with incremental doses of midazolam and fentanyl. Intradermal lidocaine was used at the site of needle insertion. The superior aspect of the spinous process above the nerve to be blocked was located and the overlying skin marked. Three centimeters lateral to this, another skin mark was made to localize the transverse process of the immediately caudad vertebra. A spinal needle was inserted at this level and advanced to identify the transverse process. The needle was then moved caudad off the transverse process and inserted into the paravertebral space (Fig. 2). Four milliliters of 0.5% bupivicaine with 1:400,000 epinephrine was injected at each paravertebral space. Blocks adjacent to C7—T7 were performed. The patients were then transferred to the operating room. Prophylactic intravenous antibiotic (cefazolin 1 g) was given preoperatively. Intraoperative sedation was provided by diprivan infusion (50 μg/kg/minute) and intermittent doses of fentanyl, 25 μg, as needed.

After standard povodine iodine skin preparation, the planned operation was performed after testing the skin for adequate anesthesia. Mastectomy was performed through transverse or oblique incision, skin flaps were created using electrocautery and the breast, and pectoralis fascia were excised from the chest wall. Axillary dissection as an indepen-

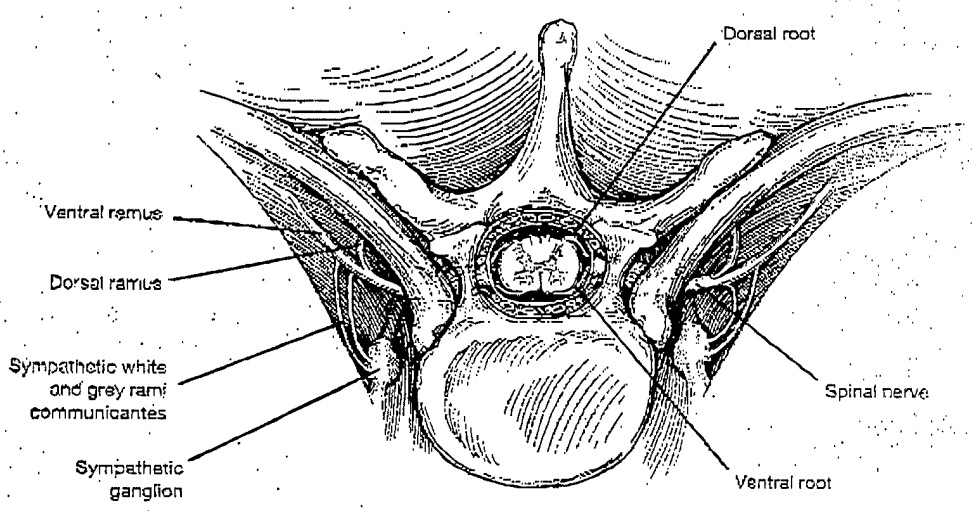


Figure 1. The origin and distribution of spinal nerve are shown. The thoracic paravertebral space includes the spinal nerve at the site of division into dorsal and ventral rami, the sympathetic ganglion, and the sympathetic white and grey rami communicantes of the ventral ramus.

dent procedure was performed through an incision extending from pectoralis muscle border to latissimus dorsi. Level I and II nodes were included in the dissections. Mastectomy wounds were drained with two closed suction catheters (10 mm round Blake, Johnson & Johnson Medical, Inc., Arlington, TX), one placed in the axilla and one beneath skin flaps. Axillary dissection wounds were drained through a single catheter. All operative specimens were submitted for permanent pathologic analysis. In selected cases, frozen section analysis was used to assess margins of resection.

The patients were evaluated in the recovery room with regard to appropriateness for discharge. Oral antibiotic (cephalexin, 500 mg four times daily) was prescribed until drain removal. Naproxen (500 mg twice daily for 4 days) was prescribed as a standing order for postoperative analgesia and acetaminophen and codeine (30 mg) tablets were prescribed if needed. Before discharge, the patients were given oral and written instruction on wound and drain care and expected drainage output. They were contacted by telephone during their recovery and were questioned on duration of sensory block, nature of postoperative pain, narcotic use, and presence of nausea and vomiting. Each was asked to rate their overall experience of breast surgery with paravertebral block as "very satisfactory," "satisfactory," or "unsatisfactory."

Patients were seen at the outpatient breast clinic

Table 1. PATIENT CHARACTERISTICS

Patient No.	Age (yrs)	Preoperative Cancer Stage	Operative Procedure	Discharge Status
1	63	Stage II	Wide excision and ALN	Ambulatory
2	49	DCIS	Simple mastectomy	Planned overnight observation
3	46	Stage II	Wide excision and ALN	Ambulatory
4	39	Stage II	Modified radical mastectomy	**Ambulatory,** admitted for nausea
5	57	Stage I	Modified radical mastectomy	Ambulatory
6	69	Stage II	Modified radical mastectomy	Planned overnight observation
7	67	Stage I	Simple mastectomy	Ambulatory
8	50	Stage I	Wide excision and ALN	Ambulatory
	50	Stage I	Simple mastectomy	**Ambulatory,** admitted for bleed
9	62	Stage I	Modified radical mastectomy	**Ambulatory,** admitted for pain
10	45	Stage I	Wide excision and ALN	Ambulatory
11	53	Stage II	Wide excision and ALN	Ambulatory
12	56	Stage I	Wide excision and ALN	Ambulatory
13	77	Stage I	Modified radical mastectomy	Planned overnight observation
14	70	Stage I	Simple mastectomy	Ambulatory
15	59	Stage II	Wide excision and ALN	Planned overnight observation

ALN = axillary lymph node dissection; **Ambulatory** = indicates original planned discharge status; DCIS = ductal carcinoma *in situ*.

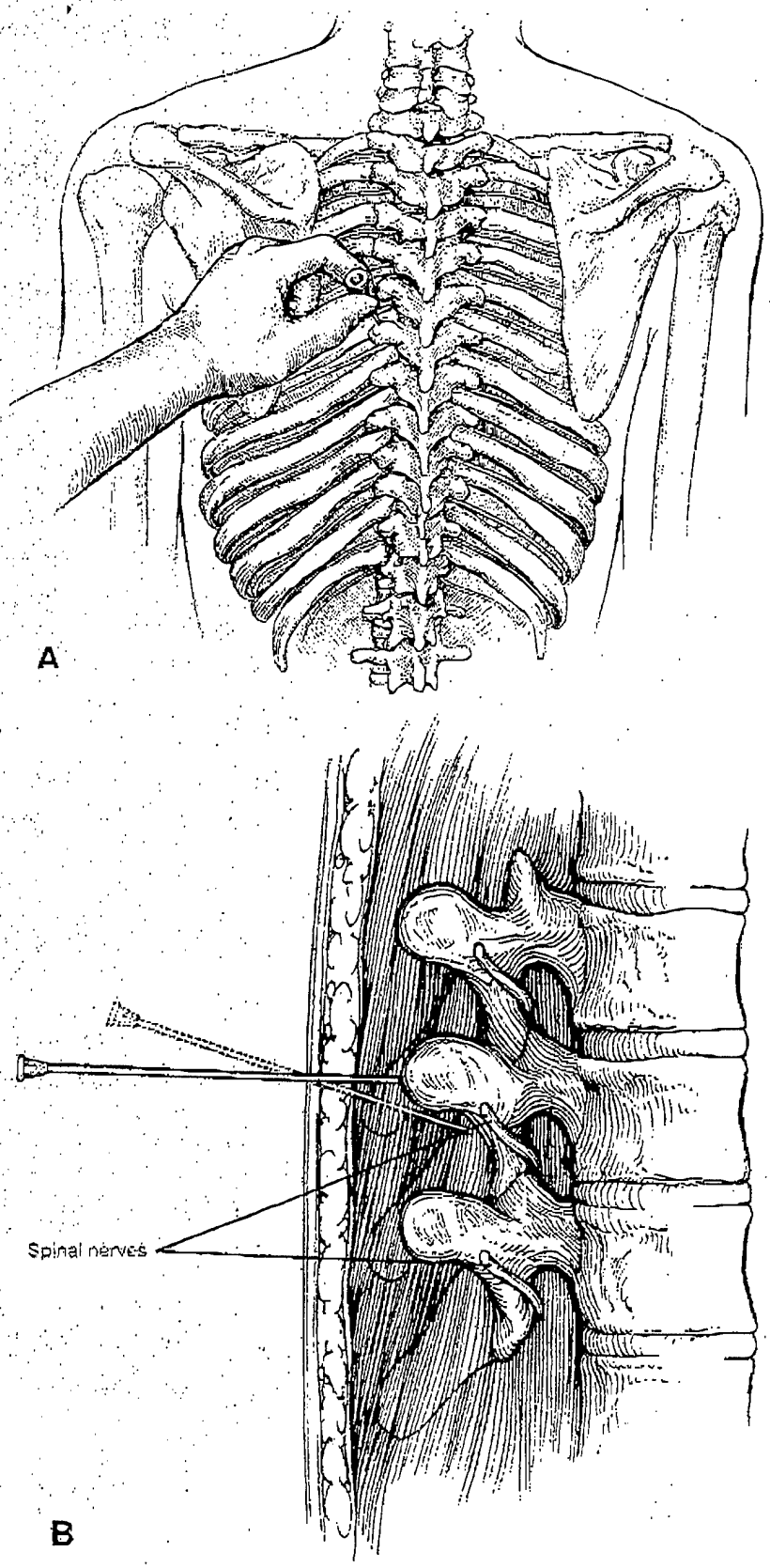


Figure 2. The technique of paravertebral block practiced in this series is shown. (A) The spinal needle is inserted at the level of the transverse process of the paravertebral space to be blocked. (B) The spinal needle is "walked" caudad off the transverse process, then inserted into the paravertebral space for injection.

within 10 days and thereafter as needed for wound examination, drain removal, and consultation in selected cases with radiation and medical oncologists. Drains were removed when output was less than 30 mL per day. Itemized patient charges were obtained from the Department of Surgery billing office, and excluded professional surgical and anesthesia fees.

RESULTS

The operative time averaged 76 minutes for simple mastectomy, 116 minutes for modified radical mastectomy, and 122 minutes for wide local excision with axillary dissection. There were no intraoperative complications. Pathologic analysis revealed negative margins in all local excisions and mastectomy specimens. An average of 16 lymph nodes were identified in mastectomy specimens and 20 in axillary dissection specimens.

Fifteen of the 16 paravertebral blocks produced complete anesthesia. One block was deficient. A 62-year-old patient had intermittent sharp pain during the initial skin incision for modified radical mastectomy. This was attributed to incomplete blockade of all spinal nerve levels. The patient was further sedated with ketamine, no further discomfort was noted, and the patient tolerated the remaining portion of the procedure well. She subsequently rated the anesthetic experience as "very satisfactory." One patient experienced intraoperative agitation and disorientation. She also was sedated with ketamine and the procedure was completed successfully. She subsequently rated the anesthetic experience as "very satisfactory."

In 9 of 11 cases, patients scheduled for ambulatory surgery were discharged home after an average recovery room stay of 169 minutes. All patients who underwent planned admission for postoperative observation were discharged by the morning after operation, and one patient was discharged within 4 hours of operation.

There was one early postoperative complication. A 50-year-old woman discharged from the recovery room after simple mastectomy noted wound swelling and excessive bloody drainage. She presented promptly and was taken to the operating room, where wound hematoma was evacuated and a subcutaneous bleeding vessel was ligated. She was subsequently hospitalized for intravenous antibiotics with no further complications.

Nausea and vomiting complicated the recovery of three patients. A patient scheduled for discharge after modified radical mastectomy experienced nausea and vomiting after ingesting acetaminophen and codeine in the recovery room and was subsequently admitted for control of nausea and intravenous fluids. She had no further episodes of nausea and vomiting. One patient had an isolated episode of nausea and vomiting while being driven home from the hospital. A third patient had a transient episode of nausea after ingesting acetaminophen and codeine at home.

The patient with incomplete paravertebral block required intravenous narcotic in the recovery room and was an unplanned admission overnight for observation and pain control. With the exception of this patient with an incomplete sensory block, no patients required intravenous narcotics in the postoperative period. Paravertebral block provided analgesia for an average of 23 hours (range 9–38 hours). Patients typically described localized stiffness after resolution of the block. Nine patients required no oral narcotic to supplement naproxen, three took acetaminophen and codeine 1 to 2 times, and three took acetomenophin and codeine more than 3 times.

Drains were removed on an average at day 7. The axillary drain of a 77-year-old patient was inadvertently pulled at home 3 days after modified radical mastectomy. Three late complications occurred. Wound seroma was detected during postoperative visits of two patients, including the patient with inadvertent drain removal. Both were aspirated, and neither required repeat aspiration. One wound infection, manifest as incisional erythema, resolved after outpatient treatment with oral antibiotics.

Fourteen of 15 patients rated the overall surgical, anesthetic, and recovery experience as "very satisfactory." Patients typically expressed pleasure at the ability to return home and stressed the ease of recovery. Those who had prior experience with general anesthesia expressed a distinct preference for paravertebral block. A 49-year-old patient who underwent simple mastectomy rated the experience as "unsatisfactory." Although she tolerated the procedure well, she later described nervousness at having been aware of events during the operation and expressed a distinct preference for general anesthesia.

Average hospital charges were $2938 for ambulatory patients and $3764 for patients admitted overnight. Room charges for the latter group averaged $412, representing 11% of total charges. Recovery room charges, determined by length of stay, averaged $210 for ambulatory patients and $101 for those admitted. Operating room and anesthetic charges, operative supplies, and pharmaceuticals constituted the remainder, and majority, of costs (Table 2).

DISCUSSION

Prior studies investigating the potential for cost containment have established the safety of recovering from breast surgery as an outpatient. Cohen,[3] Orr,[4] Litvak,[5] and Edwards[6] found no increased morbidity among patients discharged with indwelling drains *versus* patients hospitalized until drain removal. These studies estab-

Table 2. AVERAGE HOSPITAL CHARGES IN DOLLARS FOR AMBULATORY AND OVERNIGHT OBSERVATION PATIENTS

	Operating Room Occupancy	Anesthesia Fee	Pharmacy Fee	Supplies	Recovery Room	Overnight Room	Total
Ambulatory	1362	961	227	178	210	—	2938
Planned overnight observation	1539	974	401	337	101	412	3764

lished the guidelines for patient instruction in wound and drain care at home, and we continue to adhere strictly to these. Further reduction of hospitalization by performing breast surgery as an ambulatory procedure or followed by an overnight stay was practiced equally safely in these 15 patients. The incidence of wound infection (6%) and seroma (12%) were lower than those reported for patients undergoing prolonged hospitalization,[12-13] and there were no complications involving flap ischemia or dehiscence. The episode of early postoperative hemorrhage was immediately recognized and acted on by the patient. Reoperation was undertaken without delay, and outpatient status did not prove detrimental. This case illustrates the necessity of selecting patients for ambulatory breast surgery whose ability to respond to postoperative complication is not limited by comorbid disease or distance from medical care.

Anesthetic side effects and complications have limited early discharge after breast surgery for patients otherwise able to recover at home. Nausea and vomiting complicate 20% to 50% of all operative procedures,[7,14] with the highest incidence occurring in patients undergoing general anesthesia, in female patients and in patients undergoing breast surgery. Nausea and vomiting increase costs both by prolonging recovery room and hospital stays. They also have been described by patients as more debilitating than the overall surgical procedure.[14] In our experience, postoperative incisional pain generally requires parenteral narcotic for patients undergoing major breast procedure under general anesthesia. In addition to the desire to obviate patient discomfort, the need for hospitalization, increased costs, pain-induced hypertension, and exacerbation of nausea and vomiting have prompted efforts to block immediate postoperative pain in this group.[7,15-16]

Various local and regional anesthetic techniques have been described for breast surgery and promoted as alternatives to general anesthesia.[15-18] Reports emphasize that these techniques are conducive to ambulatory status, minimizing postoperative nausea, vomiting, and pain. Specific techniques, however, have deficiencies. Field block and local anesthetic infiltration were first used for breast biopsy in the 1960s and have largely replaced general anesthesia for isolated limited breast excisions.[17-18] Attempts to apply local techniques to mastectomy and other major breast procedures, however, are limited by pain with injection, tissue distortion, and risk of local anesthetic toxicity.[15-16,19] Intercostal nerve block enables effective anesthesia and prolonged analgesia for simple mastectomy and plastic surgical procedures, such as augmentation and reduction mammoplasty.[15] The classic technique of injecting levels T3 to T7 in the midaxillary line effectively blocks the breast tissue and anterior chest wall. The scapula, however, interferes with injection of levels T1 and T2 at the midaxillary line, and this precludes axillary anesthesia and regional lymph node dissection.[9] High thoracic epidural provided adequate intraoperative anesthesia in a series of patients undergoing augmentation mammoplasty.[16] This technique cannot provide prolonged postoperative analgesia without maintaining the epidural for ongoing injections because of rapid vascular uptake within the epidural space. Once the epidural catheter is removed, no postoperative analgesia is achieved, necessitating supplemental oral or parental analgesics. Furthermore, risks of spinal cord injury and complete sympathetic blockade causing hypotension have prompted cautionary criticism.[20]

Paravertebral block obviates these deficiencies. Sympathetic blockade is unilateral; hence, although a transient ipsilateral Horner's syndrome may develop, there is minimal risk of epidural spread of local anesthetic and complete sympathetic blockade.[11] The relative avascularity of the paravertebral space limits anesthetic diffusion and allows prolonged sensory block and effective postoperative pain control. In fact, pain control for up to 20 hours after operation can be achieved without supplemental oral or parental analgesics. As opposed to intercostal injection, the lower cervical and upper thoracic paravertebral spaces are accessible, enabling effective anesthesia of the axilla.

Paravertebral block was employed successfully in this initial series of patients undergoing simple mastectomy, modified radical mastectomy, and local excision with axillary dissection. None of the described complications of paravertebral block, pneumothorax, local anesthetic toxicity, puncture of the subarachnoid space, or intravascular injection occurred.[9,11] Paravertebral blockade in conjunction with sedation provided adequate anesthesia.

The patient with incomplete blockade and the patient with intraoperative agitation were adequately sedated with ketamine. Neither conversion to general anesthesia nor supplementation with local anesthesia was required. Thus far, no patients have been encountered in whom performance of paravertebral block was not feasible, and, other than bleeding disorders, no contraindication to its use has been identified.

Surgical technique, operative time, and adequacy of resection, as evidenced by margins of resection and lymph node retrieval, were not compromised.

Nausea and vomiting had only a transient effect in the three patients affected. It prompted hospitalization in only one patient originally scheduled for an ambulatory operation, and in two patients, nausea and vomiting followed and are possibly attributable to narcotic ingestion. Equal success was achieved regarding postoperative pain control, as evidenced by duration of block, minimal narcotic use, and need for hospitalization in only one patient.

An analysis of costs of patients undergoing breast procedures under paravertebral block provides a stark contrast to prior studies in which cumulative inpatient room charges constituted the majority of total costs.[5-6] Room charges averaged 11% of the total charge for patients admitted to postoperative observation rooms. This reflects early discharge of these patients and the policy of prorated room charge that minimizes costs if the patient chooses to be discharged from the hospital room as early as the day of operation. Charges for hospitalized patients can be further reduced by avoiding the recovery room. Patients currently are being transported directly from the operating room to inpatient observation room if they are stable and adequately reversed from sedation, thus far without any problem. Although the average overall charge for patients discharged home from the recovery room was lower than those admitted overnight, further savings can be achieved in the ambulatory setting. Intensive monitoring and nursing are not required after paravertebral block, rather, ambulatory patients generally require observation, comfort measures, and discharge instruction. Recovery room charges for ambulatory patients should be adjusted to reflect the minimal level of care required after paravertebral block.

It is predicted that 182,000 women will be diagnosed with breast cancer in 1995[21] and most patients will undergo a major surgical procedure. In 1991, the average daily inpatient cost for hospital stay was $745.[1] Since the beginning of same-day admission and early discharge policies in 1986, hospital stays have averaged between 2.6 and 5.5 days after major breast surgery.[2-6,22] Although these shortened stays resulted in significant savings relative to prior practices, an even more dramatic reduction in nationwide costs can be achieved through ambulatory surgery or overnight stay after paravertebral block.

The most meaningful aspect of this initial experience with paravertebral block has been patient satisfaction. In promoting ambulatory hernia surgery, Wantz wrote that "the mere idea of ambulatory surgery softens the emotional impact of the operation and thereby redefines disability by encouraging the patient to get on with his life."[23(pp1228-1229)] This tenet is all the more applicable to the population of women, many young and otherwise healthy, undergoing surgical treatment of breast cancer. The ability to avoid hospitalization and recover at home without pain, nausea, and vomiting softens the impact of a cancer diagnosis and encourages early return to normal activity or initiation of further treatment. Paravertebral block has achieved these goals. This is reflected both in patients' nearly uniform rating of this technique as very satisfactory, and, more importantly, the enthusiasm and gratitude with which they recall their operative and recovery experience. It also is reflected in the willingness expressed by new patients as our experience with paravertebral block continues and they are presented with the option of effective regional anesthesia and immediate or early discharge.

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